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CASE REPORT

Concurrent Vismodegib and Hypofractionated Stereotactic Radiotherapy in a Patient with Recurrent Locally Advanced Basal Cell Carcinoma: Case Report*

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ABSTRACT

In this study, we present a patient with recurrent basal cell carcinoma (BCC) located in a high-risk area of the face who was treated with a combination of vismodegib and hypofractionated stereotactic radiotherapy (hSRT). Targeted therapies such as hedgehog pathway inhibitors play an important role in the treatment of advanced BCC, but the duration of response is limited due to resistance. The combination of hedgehog pathway inhibitors and radiotherapy has the potential to achieve a durable and effective therapeutic response, particularly in patients with locally advanced disease. A 68-year-old male patient had a recurrent mass localized to the nasal dorsum and extending to the medial canthus of both eyes, infiltrating the nasal and maxillary bones. Multiple biopsies taken from the lesion edges reported infiltrative BCC and basosquamous cell carcinoma foci. The patient responded well to vismodegib, but surgery was not considered. Considering the tolerance of the organs at risk, concurrent 4200 centigray/14 fractions hSRT was applied with the CyberKnife-M6 device. Acute grade 1 to 2 toxicity was observed during treatment. At the end of treatment, the mass regressed, ptosis in the left eye decreased, and the visual field expanded. Complete radiological and clinical response was achieved four months after treatment. Combination therapy was found to be effective in a patient with recurrent locally advanced BCC. The combination of vismodegib and hSRT should be evaluated in prospective studies.

Keywords: Basal cell carcinoma. Stereotactic radiotherapy. Vismodegib.

Lokal İleri Yinelemiş Bazal Hücreli Karsinom Tanılı Bir Olguda Eşzamanlı Vismodegib ve Hipofraksiyone Stereotaktik Radyoterapi: Olgu Sunumu

ÖZET

Bu çalışmada, vismodegib ve hipofraksiyone stereotaktik radyoterapi (hSRT) kombinasyonu ile tedavi edilmiş olan yüzün yüksek riskli bölgesinde yerleşmiş yinelemiş bazal hücreli karsinom (BHK)' lu bir hasta sunulmaktadır. Hedgehog yolu inhibitörleri gibi hedeflenmiş tedaviler, ileri evre BHK tedavisinde önemli bir rol oynar, ancak direnç nedeniyle yanıt süresi kısadır. Hedgehog yolak inhibitörleri ve radyoterapinin kombinasyonu, özellikle lokal ileri evre hastalarda kalıcı ve etkili bir tedavi yanıtı sağlama potansiyeline sahiptir. 68 yaşında bir erkek hastada, nazal dorsuma lokalize ve her iki gözün medial kantusuna kadar uzanan, nazal ve maksiller kemikleri infiltre eden nüks kitle mevcuttu. Lezyon kenarlarından alınan çoklu biyopsiler, infiltratif BHK ve bazoskuamöz hücreli karsinom odakları şeklinde raporlanmıştı. Vismodegib'e iyi yanıt veren hastaya cerrahi düşünülmemişti. Risk altındaki organların toleransı göz önüne alınarak CyberKnife-M6 cihazı ile eşzamanlı 4200 santigray/14 fraksiyon hSRT uygulandı. Tedavi sırasında akut derece 1-2 toksisite gözlendi. Tedavi sonunda kitle geriledi, sol gözdeki pitozis azaldı ve görme alanı genişledi. Tedaviden 4 ay sonra radyolojik ve klinik tam yanıt elde edildi. Tekrarlayan lokal ileri evre BHK'lu bir hastada kombine tedavi etkin bulundu. Vismodegib ve hSRT kombinasyonu ileri prospektif çalışmalarla değerlendirilmelidir.

Anahtar Kelimeler: Bazal hücreli karsinom. Stereotaktik radyoterapi. Vismodegib.

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Keratinocyte carcinomas, which include basal cell carcinoma (BCC) and squamous cell carcinoma (SCC), are the most commonly diagnosed cancers worldwide[1]. BCC accounts for 65–80% of cases and has an incidence rate of 525 per 100,000 individuals[1, 2]. It is more frequently observed in fair-skinned males over the age of 65. Etiologic factors include ultraviolet radiation exposure, ionizing radiation, immunosuppression, chronic inflammation, hereditary syndromes, and family history[1]. Although treatment decisions are primarily based on the risk stratification of the patient and tumor characteristics, surgery remains the first-

line treatment. In low-risk cases, surgical treatment is usually sufficient, with reported 5-year recurrence rates of 2–3.5%[1]. For patients unsuitable for surgery or with specific tumor locations, non-surgical modalities such as cryotherapy, electrodessication and curettage, topical agents, photodynamic therapy, and laser treatment may be employed. However, these options present a wide range of 5-year recurrence rates, varying between 5% and 30%[1].

Radiotherapy (RT) can be considered an alternative to surgery for small tumors, and is also recommended for unresectable cases or when postoperative pathologic risk factors are present. Reported 5-year local control (LC) rates are 95% in early-stage and 56% in advanced-stage cases[3]. However, RT is contraindicated in the presence of connective tissue diseases and genetic predispositions, and is generally not recommended for patients under 60 years of age. Chemotherapy shows limited efficacy in aggressive, unresectable, or metastatic cases, with response rates below 30%[1]. Mutations in the sonic hedgehog (SHH) signaling pathway are identified in approximately 85% of patients with BCC[4]. Current treatment strategies involve molecular targeted therapy with hedgehog inhibitors (HHIs) such as vismodegib and sonidegib[5,6]. In the ERIVANCE study, 104 patients received vismodegib treatment for a median duration of 13 months, during which objective response rates of 48% in locally advanced and 33% in metastatic cases were reported[5]. However, the duration of response ranged between 7.6 and 9.5 months and was associated with the development of resistance. Furthermore, 17% of patients discontinued therapy due to adverse effects such as muscle spasms, alopecia, dysgeusia, weight loss, fatigue, and nausea.

The addition of RT to vismodegib has been proposed to overcome treatment resistance and enhance therapeutic response. In an experimental study by Hehlgans et al., vismodegib demonstrated radiosensitizing properties[7]. Case-based studies have reported meaningful clinical benefits with either sequential or concurrent combinations of HHIs and RT[8-10]. Barker et al. administered conventional RT at doses of 66–70 gray (Gy) in 33–35 fractions (fx) concurrently with vismodegib following 12 weeks of systemic therapy, which had already achieved a 63% response rate in 24 patients[11]. After RT, the response rate rose to 83%, with reported 5-year locoregional control, progression-free survival (PFS), and overall survival (OS) rates of 91%, 78%, and 83%, respectively.

A meta-analysis evaluating studies that applied hypofractionated RT using modern techniques reported favorable cosmetic outcomes in 80% of patients, and 5-year LC rates of 85%[12]. In periorbital, case-based studies, stereotactic radiotherapy achieved complete responses while preserving visual functions[13,14]. The new-generation CyberKnife-M6 (CK-M6) system, which enables non-isocentric real-time image-guided treatment delivery, offers a more comfortable option due to shorter treatment durations, and allows for better sparing of organs at risk[15].

In this report, we present a case of locally advanced periorbital BCC treated with concurrent vismodegib and CK-M6–based hypofractionated stereotactic radiotherapy (hSRT), with a significant therapeutic response at the end of treatment.

Case Report

A 68-year-old male patient had undergone four surgical procedures at an external center for a lesion diagnosed as SCC that had been present on the nasal dorsum for 35 years. In a positron emission tomography/computed tomography (PET/CT) scan performed in December 2020, skin-subcutaneous activity on the nasal dorsum was reported (SUVmax = 5.81). A biopsy from the same month revealed a 0.8 cm SCC with positive surgical margins, and the patient was followed up without further intervention.

In November 2023, cranial magnetic resonance imaging (MRI) showed a 3 × 2.5 cm centrally located mass on the nasal dorsum, extending prominently to the medial canthus of both eyes, infiltrating both nasal bones and the left maxillary bone (Figure 1A). Multiple biopsies obtained from the lesion margins—left eyebrow (1.5 cm), left lateral nose (1.4 cm), right lateral nose (0.8 cm), and right eyebrow (1 cm)—revealed infiltrative BCC and bazoSCC foci.

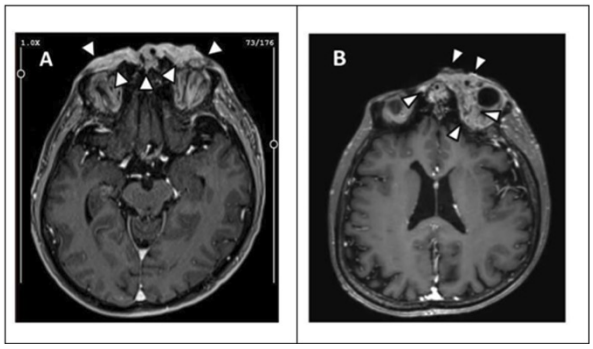

Figure 1: (A)
Axial contrast-enhanced T1-weighted cranial MRI from November 2023: " 3 × 2.5 cm multilobulated mass localized to the nasal dorsum, extending to the medial canthus of both eyes, infiltrating both nasal bones and the left maxillary bone, causing destruction and associated with widespread skin irregularity."
(B) *Axial contrast-enhanced T1-weighted cranial MRI from July 2024, prior to stereotactic radiotherapy.*

Concurrent vismodegib and RT

After receiving one cycle of docetaxel, cisplatin, 5-fluorouracil, and folinic acid, the patient was started on vismodegib 150 mg once daily, has been using it for 8 months. As a response was observed (Figure 1B), surgery was not considered, and the patient was referred to our department for RT.

At clinical examination in July 2024, a crusted lesion with mild discharge was noted at the midline of the nasal dorsum and glabella, measuring 5 cm in length, 3 cm in width, and 1 cm in height (Figure 2A). Neurological examination revealed reactive light reflexes bilaterally, preserved vision and ocular movements; however, the left eyelid was ptotic and could not fully open. The Karnofsky performance score was 80. The patient had no comorbidities, a 30 pack-year smoking history, and no significant family history. Informed consent was obtained for concurrent vismodegib and RT.

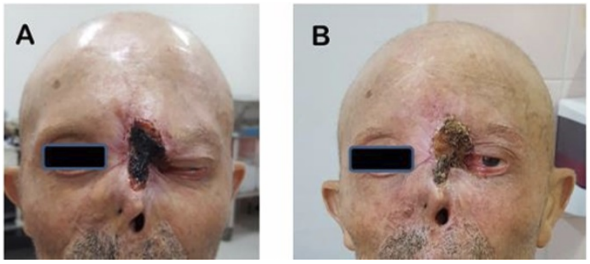

Figure 2: (A)
Pre-treatment: A 5 × 3 cm ulcerated lesion with mild discharge located at the midline of the nasal dorsum and glabella. ***(B)*** *Post-treatment: The lesion has regressed to 4 × 2.5 cm, and improvement in left eyelid ptosis is observed.*

The patient was immobilized with a non-invasive mask. Contrast-enhanced cranial MRI with 1 mm slice thickness was acquired and co-registered with the planning CT. A planning target volume (PTV) was created by adding a 10 mm margin to the gross tumor volume and adjusted according to anatomical landmarks. Taking organ at risk (OAR) tolerance into account, hSRT was planned at 4200 cGy in 14 fx. %95 of the PTV received 4200 cGy at the 87.7% isodose line. Fraction duration, coverage, homogeneity index, and conformity index were 19 minutes, 94.97%, 1.14, and 1.15, respectively. Biologically effective dose (BED) values were BED_{10} = 54.6 Gy for tumor tissue and BED_3 = 84 Gy for normal tissue. All OAR doses were within tolerance except for the maximum dose to the left eye. Dosimetric details are provided in Table I.

Table I. Dosimetric findings. GTV: Gross tumor volume, PTV: Planned target volume, fx= fraction.

Parameters	Volume max (cGy)	Mean (cGy)	Maximum (cGy)	Tolerance dose limits for 15 fx (Timmerman 2022)	
				Mean/ volume (cGy)	Maximum (cGy)
GTV (29.75 cm3)	4200	4405	4771		
PTV (62.85 cm3)	4200	4385	4789		
Right eye		799	3126	Mean ≤ 3300	3750
Left eye		2070	4233	Mean ≤ 3300	3750
Right lens		298	391		900
Left lens		509	637		900
Right optic nerve	884	959	1088	< 0.5 cm3 = 3900	4200
Left optic nerve	813	1400	2711	< 0.5 cm3 = 3900	4200
Chiasm	650	687	885	< 0.5 cm3 = 3900	4200
Brainstem	169	119	290	< 5 cm3 =4000	4400
Spinal cord	92	101	177	< 5 cm3 =3900	4200

Treatment was delivered on the CK-M6 system using real-time image guidance with imaging every 20–60 seconds (Figure 3). The total treatment duration was 19 days, with weekly physical examinations during RT. Acute Grade 1 ocular dryness and conjunctivitis, and Grade 2 erythema were observed and managed symptomatically. By the end of treatment, the lesion had regressed to 4 × 2.5 cm, left eye ptosis had resolved, and the visual field had improved (Figure 2B). In the follow-up cranial MRI performed in February 2025, four months after hSRT, complete response was achieved, with mild skin maceration observed at the treatment site (Figure 4).

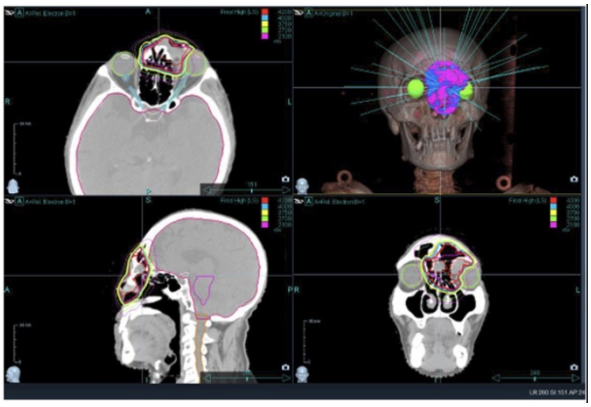

Figure 3:
Treatment plan (CyberKnife-M6)

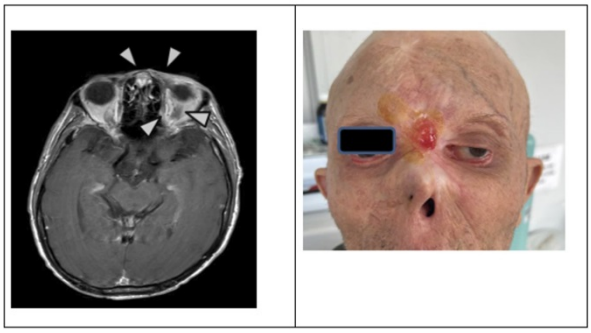

Figure 4:
At four months post-treatment, the left side of the figure shows cranial MRI demonstrating complete response, while the right side shows mild maceration in the glabellar region on clinical examination.

Discussion and Conclusion

This report presents the outcomes of concurrent hSRT and vismodegib treatment in a patient with locally advanced, recurrent BCC in the periorbital region who had previously undergone multiple surgeries.

Surgery is the gold standard in the treatment of BCC. In a randomized study comparing surgery and RT for tumors <4 cm, 4-year recurrence rates were 0.7% vs. 7.5%, respectively, with superior cosmetic outcomes reported for surgery (87% vs. 69%)[16]. On the other hand, a meta-analysis by Drucker et al. reported a local recurrence rate of 3.5% with RT, comparable to surgical outcomes[17]. Besides staging, tumor diameter, and histology, anatomical location has also been emphasized as a prognostic factor, with facial sites being considered moderate- to high-risk areas[18]. In periorbital tumors, due to medial canthus location, multiple recurrences, large tumor size, aggressive histology, and advanced age, orbital invasion occurs in 2–4% of cases, and approximately 5.5% of patients require orbital exenteration[19]. In cases requiring extensive surgery, incomplete resection, or medically inoperable locally advanced disease, RT serves as an effective alternative, allowing for preservation of organs and function.

RT for keratinocyte tumors can be delivered using various modalities such as electrons, orthovoltage/megavoltage photons, or brachytherapy[18]. In BCC, LC rates have been reported as 90% for primary tumors and 80% for recurrent cases[18]. To achieve 90% LC, it is recommended to deliver 45–60 Gy for tumors ≤2 cm and 64–70 Gy equivalent dose in 2 Gy fractions (EQD2) for tumors 2–3 cm in size[20]. Locke et al., in a cohort of 468 patients—mostly BCC—showed that tumors >1 cm had improved LC when treated with fraction doses >2 Gy and total doses >60 Gy[21]. Conversely, Silva et al. noted that when treating target volumes >5 cc, using fraction doses <4 Gy reduced late toxicity; however, LC decreased with every 5 Gy reduction in BED[22].

In locally advanced, metastatic, or nodal disease not suitable for surgery or RT, systemic therapy is recommended. Most sporadic BCCs harbor somatic mutations in the hedgehog pathway[4,23]. Randomized studies with HHIs like vismodegib and sonidegib have reported response rates of 60–70%, with adverse events seen in 25–32% of cases[5,6]. However, due to short response durations, combining systemic therapy with local modalities such as RT has been proposed to enhance efficacy[7,23]. In a preclinical study by Hehlgans et al., combined vismodegib and RT in cell cultures significantly reduced the expression of SHH target genes such as glioma-associated oncogene homologue (GLI1) and the apoptosis inhibitor survivin, suggesting a meaningful radiosensitizing effect[7].

Several case-based studies have explored the combination of vismodegib and RT. Gathings et al. reported outcomes in an 81-year-old patient with multiple BCCs and SCCs on the face, trunk, and extremities who received 10 weeks of vismodegib (150 mg/day), resulting in complete responses in most lesions. Partial responders were treated with 60 Gy intensity modulated RT or 40–48 Gy electron RT over seven weeks. At one-year follow-up, lesions showed complete response or marked regression, making surgical resection feasible[8]. In another study, Pollom et al. treated three lesions in two patients with recurrent periorbital BCC using conventional (50–66 Gy/33 fx) or hypofractionated (51 Gy/17 fx) RT concurrent with vismodegib. Clinical responses were observed with preserved visual function and PFS of 9–12 months[9]. Block et al. reported a 7 cm facial BCC involving skin, soft tissue, and buccal mucosa requiring extensive surgery. After four months of vismodegib (150 mg/day), >50% response was achieved, followed by concurrent 50 Gy/20 fx RT. The residual 1.5 cm lesion was locally resected and showed focal BCC with negative margins[10]. Another report described a patient with four separate lesions (left preauricular, trunk, lower extremity) treated with concurrent and adjuvant vismodegib for six months and 55 Gy/20 fx RT. All lesions achieved clinical complete response, one of which had pathological complete response, with no recurrence at 18 months[3].

Recent studies with larger cohorts further support the efficacy of combined treatment. Weissman et al. treated 12 patients who had responded to 2–3 months of HHI therapy with concurrent RT (55–60 Gy/25–30 fx). Complete response was observed in all patients, with a 40-month PFS rate of 89%. Grade 1–2 toxicity occurred in 75% of cases[23]. In another study, Barker et al. treated 24 patients with locally advanced BCC with 12 weeks of induction vismodegib, followed by concurrent conventional RT. No grade ≥3 toxicity was

reported. One-year locoregional control, and 1- and 5-year PFS rates were 91%, 100%, and 78%, respectively[11].

RT technique plays a crucial role in sparing surrounding tissues. Most studies employing concurrent vismodegib and RT have utilized conventional fractionation and conformal techniques[3,8,10,23]. Meta-analysis results suggest that hypofractionated regimens yield better cosmetic outcomes without compromising LC[12]. Commonly used regimens include 50 Gy/15 fx, 36.75 Gy/7 fx, and 35 Gy/5 fx, with BED_3 values ≤100 Gy recommended for optimal cosmetic outcomes. According to American Society for Radiation Oncology guidelines, BED_{10} values for curative-intent treatment are 70–93 Gy for conventional and 56–88 Gy for hypofractionated regimens, and 60–79 Gy vs. 56–70 Gy for postoperative RT, respectively[24]. Data on stereotactic RT are limited. In cases treated with Gamma Knife or CyberKnife, complete responses have been reported with single-fraction 15 Gy or 40 Gy in 10 fx, and a minimum of 18 Gy was suggested for durable LC in single-fraction settings[13,14].

In our case, to preserve visual function, treatment was planned in accordance with current guidelines using a 4200 cGy/14 fx hSRT regimen while accounting for OAR volume and maximum dose constraints[25]. BED equivalents were calculated as BED_{10} = 54.6 Gy and BED_3 = 84 Gy. No grade ≥3 toxicity was observed. In parallel with tumor regression, ptosis in the left eye improved and visual field expansion was noted. Follow-up cranial MRI at four months post-treatment confirmed complete response.

In conclusion, concurrent hSRT and vismodegib treatment using CK-M6 enabled effective therapy in a patient with locally advanced BCC without increasing toxicity. The impact of RT combined with HHIs on LC should be further validated through prospective, randomized trials.

Researcher Contribution Statement:
O.Ç: Case preparation, manuscript drafting, literature review, and final editing.
J.T: Assisted in case preparation and supported manuscript development.
F.G: Contributed by providing clinical data and technical details related to treatment delivery.
S.S: Initial identification of the case, major contribution to the discussion section, and critical revision of the manuscript.
Conflict of Interest Statement:
The authors of the article have no conflict of interest declarations.
Ethics Committee Approval Information:
Ethical approval was not required as this is a case report.

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