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PURPOSE

Radiation therapy can be a primary treatment option for non-melanoma skin cancer (NMSC) when function, cosmesis or patient preference makes surgery unattainable.¹ The use of isotope-based radiation therapy, particularly high-dose rate (HDR) brachytherapy, has shown to be an effective treatment option for NMSC with local control varying between 72-98%.² Recently, low energy electronic X-ray Brachytherapy (EBTx) has been used to treat NMSC. EBTx is HDR treatment making hypofractionation possible and requires minimal shielding.

Esteya[®] (Elekta AB, Stockholm, Sweden), a new FDA-cleared EBTx device for the treatment of NMSC, is a 69.5 kV device with a sharp penumbra and Surface-Skin Distance of <6 cm (orthovoltage is ≥ 15 cm). This report assesses the feasibility of EBTx for the treatment of NMSC, patient characteristics, and early outcomes (local tumor control and acute toxicity).

MATERIALS & METHODS

U.S. patients at three clinical sites started Esteya[®] EBTx treatment in January 2014 with the final patient for this report completing in October 2014. A retrospective chart review of 75 patients, with a total of 86 lesions, showed patients received a total radiation therapy dose of 45 to 50 Gy in 8 to 10 fractions (three different variations), delivered twice weekly (each fraction spaced by at least 2 days). This analysis included patient demographics, lesion size, histopathology, local control and toxicities at various follow-up times.

Figure 1 - Esteya device



RESULTS

98.7% of patients (74/75) successfully completed their planned treatment course. One subject (1.3%) terminated early due to unrelated medical events. The Esteya[®] EBTx system provided robust function and performance with all fractions delivered as planned with no technical issues. The median age of the patients (32 females, 43 males) was 76 years (range: 47 to 96 yr). The majority of lesions were on the face, ears or scalp (69/86) and all lesions had diameters less than 22 mm. All lesions were histologically determined, following punch or shave biopsy, as basal cell (N=54) or squamous cell (N=32). All applicator sizes (10mm through 30mm) were used in treatments. The treatments were well-tolerated by the patients with expected acute cutaneous reactions (e.g. erythema). There were no unexpected adverse events (AEs) or high grade AEs. Most patients (60%; 45/75) have completed 6 months of follow up; no recurrences have been observed to date.

The photos below show applicator placement markings, typical cutaneous response during treatment (fractions 4 & 8) and three months post treatment. This subject was treated with 8 fractions of 6 Gy/fx



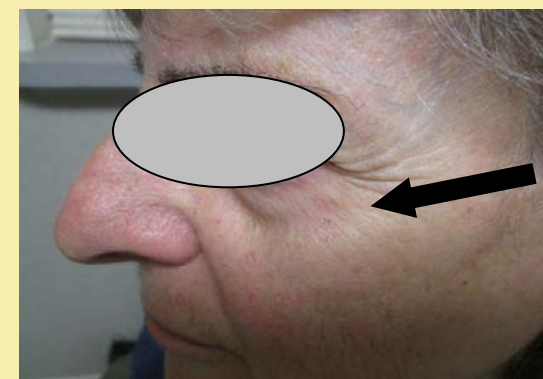
Pre-Treatment
(Basal Cell Carcinoma)



Fraction #4



Fraction #8



3-Month F/U

Nearly all patients (98%) were graded as having mild to moderate erythema on completion of the final fraction. In the acute period (0-2 months) substantial improvement in erythema occurred, with no subjects having grade 3 erythema or higher. A smaller number of subjects had a follow up visit in the 2-6 month period. Erythema rates by grade in these time periods are given in the table.

CTCAE v3 Erythema Grade	AE Grade Immediately Post-Treatment		AE Grade 0-2 Months		AE Grade 2-6 Months	
	N	%	N	%	N	%
0	1	2%	10	36%	7	88%
1	17	31%	11	39%	0	0%
2	26	48%	7	25%	1	13%
3	10	19%	0	0%	0	0%
4	0	0%	0	0%	0	0%
Total Graded	54		28		8	

To date no recurrences of the treated lesions have occurred, though 2 patients have new skin cancers diagnosed, all of which were distant (unrelated) to the treated lesion(s). Other expected cutaneous toxicities occurring immediately post-treatment and within 0-2 months, respectively: hyperpigmentation (0%; 1.3%), pruritus (6.7%; 1.3%), desquamation (8.0%; 1.3%), mild pain (6.7%; 0%) and nose bleeds (4.0%; 0%). Three patients died of unrelated causes.

CONCLUSIONS

Our initial experience at three US sites demonstrated EBTx using the Esteya[®] system to be simple and robust with excellent quality assurance and a reliable X-ray source. The treatment was well tolerated by the patients with only minor acute cutaneous toxicity and no unanticipated or severe AEs observed. At the current time, no local tumor recurrence has occurred. The patients will continue to be followed for observation and correlation of local control, toxicity and treatment parameters.

References:

- 1) NCCN guidelines. NCCN.org
- 2) Tormo, A, et al. Nonmelanoma skin cancer treated with HDR valencia applicator: clinical outcomes. *J Cont Brachyther*. 2014;6:1-6.