Rhenium-188 skin cancer therapy (SCT) Australian Subanalysis: Two-year efficacy and safety from a prospective multicentre phase IV study (EPIC-Skin)

C. Baker[1], G. Cardaci[2] , A. Hong[3], N. Mulholland[4], M Sathekge[5], K. Mokoala[5], M. Heuschkel[6], J. Tietze[6], S. Mirzaei[7], G Dahlhoff[8], S. Baxi[9].

1. St. Vincent's Hospital Melbourne, Melbourne, Australia, 2. Hollywood Private Hospital, Perth, Australia, 3. GenesisCare, North Shore Health Hub, St Leonards, Australia, 4. Kings College Hospital NHS Foundation Trust, London, United Kingdom, 5. NuMeRI, University of Pretoria and Steve Biko Academic Hospital, Pretoria, South Africa, 6. University Medical Center Rostock, Rostock, Germany, 7. Institute of Nuclear Medicine with PET-Center, Vienna, Austria, 8. OncoBeta GmbH, 9. GenesisCare, John Flynn Hospital, Tugun, Australia.

1 Background

Non-melanoma skin cancers (NMSC) are the most common malignancies worldwide. While surgical excision, including micrographic surgery, achieves clearance rates exceeding 95%, treatment may be associated with disfigurement, functional morbidity, or may not be appropriate in cases of multiple lesions, anatomically difficult locations, due to patient comorbidities or preference. Rhenium-188 skin-directed radioisotope therapy has been used clinically for NMSC since 2008, with retrospective series, pooled analyses, and prospective studies reporting high local control and favourable cosmetic outcomes. The present study built on these findings by evaluating efficacy, patient quality of life and safety in selected NMSC lesions.

2 Methods

This prospective, multicentre, single-arm phase IV study enrolled 187 adults with 1-3 biopsy-proven NMSC lesions ≤3mm deep with ≤8cm^2 area. The Australian sub-analysis included 67 patients. Patients received a single outpatient treatment with rhenium-188 therapy delivering 50 Gy to the deepest point of the lesion. Clinical response was assessed using modified RECIST criteria. Secondary endpoints included quality of life, treatment comfort, cosmesis and safety.

3 Results

Demographics

187 patients Enrolled in study
67 patients Enrolled in study
(Age: Median 71.5 years (range: 27-95 years))

171 tumours From 130 patients
82 tumours From 58 patients
with 24-month follow-up

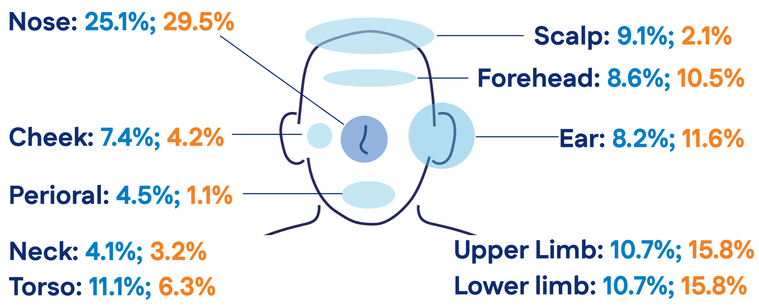
Global Australia

BCC and/or SCC:
1-8cm^2; ≤3mm deep

Fitzpatrick Type:
I (23%); II (56.7%); III (18%); IV (1.7%), V (0%), VI (0.6%)
I (11.9%); II (70.1%); III (17.9%); IV (0%), V (0%), VI (0%)

Lesion Characteristics

Rhenium-SCT single-session 50Gy treatment to depth of tumour



24 Month Outcomes

Table 1: Primary endpoint in the EPIC-Skin trial. Modified visual RECIST response categories for ITT patient tumours, based on 171 evaluable tumours in 130 patients (82 tumours in 58 patients in Australian population) with 24m follow up. Missing data are not imputed.

Category	All Tumours	BCC Tumours	SCC Tumours
Complete response	162/171 (94.7%)* 81/82 (98.8%)	123/131 (93.9%) 58/59 (98.3%)	39/40 (97.5%) 23/23 (100%)
Partial response	6/171 (3.5%) 1/82 (1.2 %)	6/131 (4.6%) 1/59 (1.7%)	0/40 (0%) 0/23 (0.0%)
Stable disease	2/171 (1.2%) 0/82 (0%)	1/131 (0.8%) 0/59 (0.0%)	1/40 (2.5%) 0/23 (0.0%)
Progressive disease	1/171 (0.6%) 0/82 (0%)	1/131 (0.8%) 0/59 (0.0%)	0/40 (0.0%) 0/23 (0.0%)

Global Australia

* Global EPIC-Skin longitudinal response analyses are undergoing final harmonisation and validation ahead of manuscript submission.

Primary Efficacy Endpoint
94.7%*; 98.8% Complete response rate

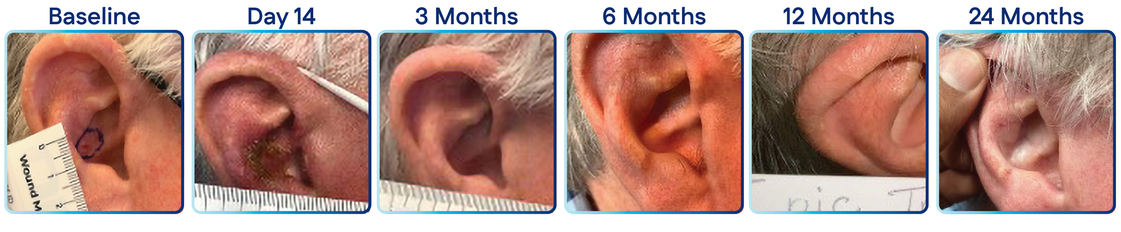
Cosmesis
8.5/10; 7.9/10 Patient-rated mean
7.9/10; 7.6/10 Clinician rated mean

QoL
+7.92 improvement in SKINDEX-16 scores from baseline

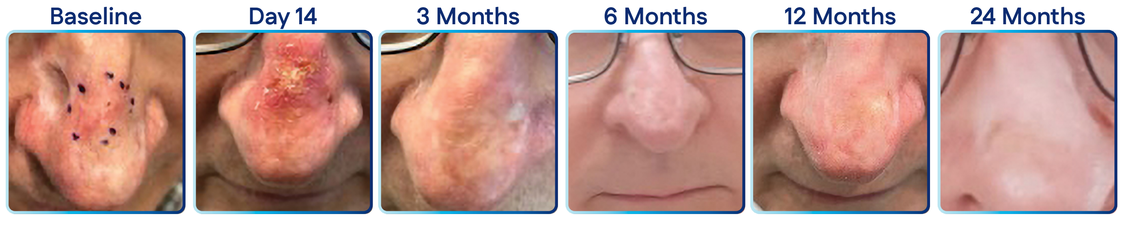
Safety
Manageable safety profile consistent with conventional radiotherapy

Typical Healing Trajectory

BCC, inner ear, 1cm^2, 1mm deep



BCC, nose bridge, 2.25cm^2, 1mm deep



SCC, hand, 7cm^2, 0.1mm deep

BCC, temple, 1.5cm^2, 2mm deep

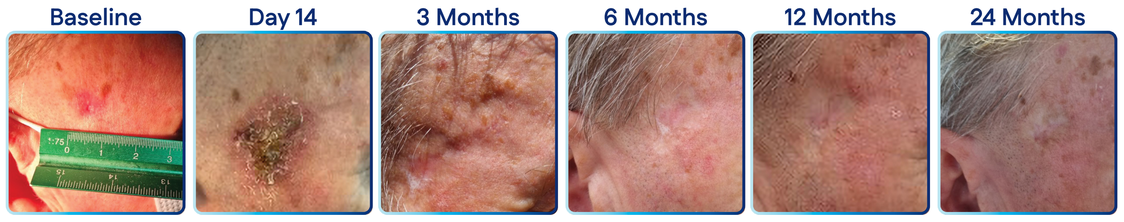
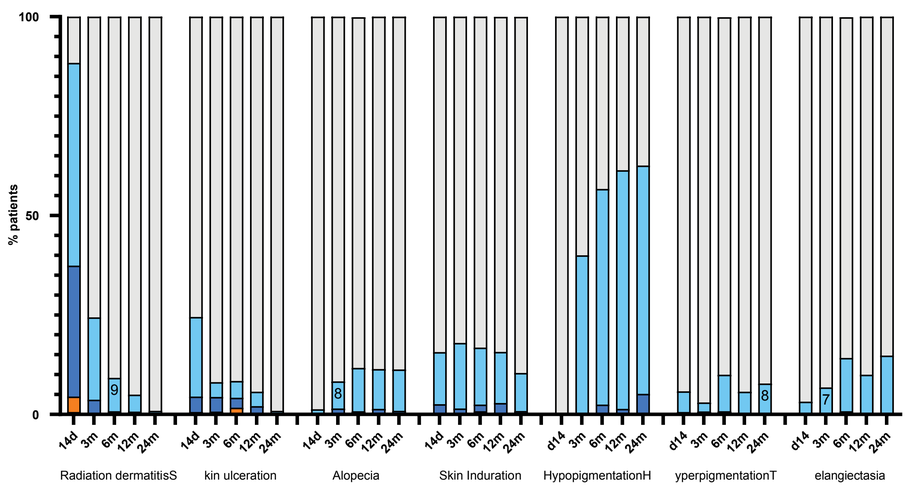


Fig. 1. Example healing profiles in EPIC-Skin over 24m follow-up.

CTCAE Adverse Events of Special Interest



Grade 3 events occurred in 2 Australian patients at 6 months, but none persisted to 12 months (1 radiation dermatitis, 1 ulceration and 1 induration).

Fig 2. Distribution of graded local skin reactions following treatment. Assessments were performed at the lesion level using four independent dermatology raters who graded early local skin reactions (A) and late local skin reactions (B) on a 0–3 scale. Median lesion-level scores across raters were categorized as Grade 1 (0.5–1), Grade 2 (1.5–2), or Grade 3 (2.5–3) and summarized descriptively. Sensitivity analyses limited to lesions with high inter-rater agreement or limited to lesions with 24m of followup demonstrated results consistent with the primary analysis (data not shown).

4 Conclusions

Rhenium-188 therapy demonstrates durable efficacy at 24 months in appropriate NMSC lesions. Follow-up shows a stable safety profile, without evidence of accumulating late skin toxicity, supporting consideration of Rhenium-188 therapy as a non-surgical option for selected superficial NMSC in patients where surgery is either contraindicated or a suboptimal treatment choice.

These findings demonstrate the high clinical benefit of Rhenium-188 treatment and support the need for transparent discussion with patients regarding expected skin changes as part of shared decision-making when considering treatment options.

References: [1] Giuseppe Cardaci, MBBS,a Siddhartha Baxi, MBBS,b Saima Vohra, PhD,c Cody Allison, PhD,d Angela Hong, MBBS,e,f Nicola Mulholland, MBBS,g Mike Sathekge, MBChB, PhD,h Kgomotso Mokoala, MBChB,h Martin Heuschkel, Dr. med.,i Julia Tietze, Dr. med.,j Siroos Mirzaei, FANM,k and Gerhard Dahlhoff, Dr. med.l,, (2025), Efficacy, Safety, and Patient Reported Outcomes of Rhenium-Skin Cancer Therapy for Non Melanoma Skin Cancer: 1-Year Results from the EPIC-Skin Study, Advances in Radiation Oncology, 101802. Rhenium-Skin Cancer Therapy (SCT) for the Treatment of Non-Melanoma Skin Cancer. (EPIC-Skin); ClinicalTrials.gov ID NCT05135052

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