Skin Cancer Research Review

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In this issue:

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Abbreviations used in this issue:

- BCC = basal cell carcinoma
- ICI = immune checkpoint inhibitor LIPS = laser-induced plasma spectroscopy
- $\label{eq:LIPS} \begin{array}{l} \text{LIPS} = \text{laser-induced plasma spectroscopy} \\ \text{MCC} = \text{Merkel cell carcinoma} \end{array}$
- $\label{eq:mms} \begin{array}{l} \textbf{MMS} = \textbf{Mohs micrographic surgery} \\ \textbf{PCP} = \textbf{primary care physicians} \end{array}$

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Welcome to issue 18 of Skin Cancer Research Review.

This review begins with a study that determined the frequency of Australians receiving consultations from general practices for skin cancer-related conditions. Another study assesses a new laser-induced plasma spectroscopy device, and its accuracy at distinguishing skin cancers from benign lesions. This review concludes with a trial that assessed an oncolytic virus, radiotherapy, and immune checkpoint-combination therapy in cancer patients, to determine whether it improves their outcomes.

We hope you enjoy this update in skin cancer research, and we look forward to receiving comments and feedback.

Best regards,

Dr David Simpson

david.simpson@researchreview.com.au

Skin cancer-related conditions managed in general practice in Australia, 2000–2016: a nationally representative, cross-sectional survey

Authors: Reyes-Marcelino G et al.

Summary: In this nationally representative study, researchers assessed the frequency of Australian general practice consultations for skin cancer-related conditions. Results were gathered from 2000-2016, and included patients 15 years or older who had skin cancer-related conditions managed by a GP. A total of 15,678 GPs had 1,370,826 patient encounters, with skin cancer-related conditions being managed 65,411 times (rate of 47.72 per 1000 encounters, 95% Cl 46.41 to 49.02). Solar keratosis (29.87%), keratinocyte cancer (24.85%), skin lesions (12.93%), nevi (10.98%), skin checks (10.37%), benign skin neoplasm (8.76%) and melanoma (2.42%) were the most commonly managed skin conditions. Management rates remained stable for solar keratoses and nevi, however increased for all other skin conditions. Patients who were aged 65-89 years, male, or living in Queensland or regional/remote areas had higher skin cancer-related encounter rates. These results highlight the burden of skin cancer-related conditions that are managed by GPs in Australia and could aid in prevention and management.

Comment: Skin cancer is mostly managed in general practice settings in Australia and is an increasing problem due to population growth, more elderly people, and outdoor lifestyle. The BEACH study – an ongoing study of general practice activity – provided data between 2000 and 2016 which confirmed the increasing skin cancer workload. Interesting findings were that more skin checks and benign lesion diagnoses were made in higher socioeconomic urban areas and more skin cancer management was performed in less affluent areas and regional areas. Queensland GP's saw the most skin cancer, and those aged 35-44 years were most likely to be treating skin cancer related diagnoses. Older males, Veterans, lower socioeconomic groups, and white-skinned individuals were most affected, which may reflect not only their higher sun exposure but possibly their lack of access to dermatologists compared to younger affluent urban populations.

Reference: BMJ Open. 2023;4;13(5):e067744. Abstract



Independent commentary by Dr David Simpson

Dr Simpson is a skin cancer doctor on the Sunshine Coast in Queensland and a teaching assistant and senior lecturer on the University of Queensland MMED Skin Cancer program. He also acts as a tutor, examiner and Blog Author for the Skin Cancer College of Australasia.

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Artificial intelligence in mobile health for skin cancer diagnostics at home (AIM HIGH): a pilot feasibility study

Authors: Smak Gregoor AM et al.

Summary: Researchers assessed the conditions and feasibility of a study which incorporated an AI-based app in primary care to detect suspicious skin lesions. A total of three primary care practices in the Netherlands utilised the AI-based mHealth app, assessing 50 patients (median age 52 years, 64% female, 90% had a light skin type). The primary outcome was successful participation for both patient and GP. After analysis, the inclusion rates for patients was 4-6 per GP practice per month, with 84% of patients (n=42) successfully participating, and in 90% of patients, the GPs also successfully completed the study. Five patients received different treatment plans, based on the app's assessment, however the GPs did not change their working diagnosis. Fifty-four percent of patients who had a benign skin lesion and had a low-risk rating indicated that they were reassured and would cancel their GP visit due to these results (p<0.001). Findings suggest that the use of an AI-based mHealth app, for the detection of skin lesions, appears to be feasible.

Comment: Artificial intelligence has been shown to be as accurate as expert dermatologists in previous studies, although the performance in real life settings as compared to analysing images is lower. This study offered an Al convolutional neural network skin lesion analysis, via a free smartphone app in members of a private health fund in the Netherlands, and examined the uptake and impact of the intervention. Images uploaded were also checked by dermatologists, and patients were messaged if it was felt that they needed a medical consultation. Only 1% (23,190 out of 2,213,212) of the invited participants uploaded images and this resulted in 73,255 uploaded skin checks, of which 21.6% were classified by the CNN as high risk. 30.7% of the "high risk" images and 2.2% of the "low risk" images were advised to seek medical attention after review. This resulted in the diagnosis of 74 basal cell carcinomas, 4 squamous cell carcinomas and 29 melanomas – "number needed to photograph" to diagnose one lesion: 990 for basal cell carcinoma (BCC), 18,314 for SCC and 2,526 for melanoma. Overall, the specificity was low, and the workload required to review images if a greater percentage of people had uploaded images would have been substantial.

Reference: EClinicalMedicine. 2023;25;60:102019. Abstract

Effect of microdoses of incisional antibiotics on the rate of surgical site infections in skin cancer surgery a randomized clinical trial

Authors: Goh M et al.

Summary: The effect of incision-site injection of antibiotic prophylaxis was assessed in this randomised clinical trial. Researchers included 681 adult patients who were presenting to a high-volume skin cancer treatment centre in Auckland, where they each received one of three treatments (buffered local anaesthetic alone [control], flucloxacillin [500 µg/mL]) or clindamycin [500 µg/mL]). Of those included (n=681; 721 total presentations, 1,133 total lesions), it was identified that the proportion of lesions that exhibited a postoperative wound infection score of \geq 5 was 5.7% (22/388) for control patients, 5.3% (17/323) for flucloxacillin patients and 2.1% (9/422) for clindamycin patients (p=0.01 for clindamycin versus control). Fewer lesions in the clindamycin arm (9/422 [2.1%], p<0.001) and flucloxacillin arms (13/323 [4.0%], p=0.03) required postoperative systemic antibiotics, compared to controls (31/388 [8.0%]). These findings highlight a significant reduction in surgical site infections with locally applied microdosed clindamycin.

Comment: Prophylactic antibiotics are sometimes used for skin cancer excisions in areas such as the ear, nose or lower legs, but systemic use is associated with disruption of the gut microbiome, resistance and adverse reactions. To overcome these problems and reduce surgical site infection, this study based in Auckland added either flucloxacillin or clindamycin to the local anaesthetic injections to provide a "microdose" directly into the wound area. At the post-operative review, there was evidence of infection in 5.7% in the control group compared to 5.3% in the flucloxacillin group and 2.1% in the clindamycin group, and antibiotics were prescribed during the follow-up period in 8% in the control group, 4% in the flucloxacillin group and 2.1% in the clindamycin group. Clindamycin has a broader spectrum against skin and soft tissue bacteria as well as activity against anaerobes that may be found in ulcerated lesions. Adding clindamycin to local anaesthetic appears safe and well tolerated and could be especially useful when operating in areas prone to infection and ulcerated lesions.

Reference: JAMA Surg. 2023;1;158(7):718-726. Abstract A multicenter prospective trial of electronic skin surface brachytherapy for keratinocyte carcinoma: Early cosmesis, quality of life, and adverse events

Authors: Kuo AM et al.

Summary: Within this prospective, multicentre clinical trial, researchers characterised early outcomes of electronic skin surface brachytherapy in patients with keratinocyte carcinoma. A total of 102 patients (≥ 60 years old) with stage T₁N₀M₀ keratinocyte carcinoma were included, and were each treated with electronic skin surface brachytherapy. Cosmesis and QoL results were collected at 97% (99/102) of patient follow-up times. 93.9% (31/33) of patient-reported and 96.9% (31/32) of clinician-reported cosmesis outcomes were 'good', 12 weeks post treatment. Additionally, total Skindex-16 scores were shown to decrease significantly 2 weeks post-treatment (10.5 versus 24.5, p<0.001), however increased at 6 weeks (10.5 versus 4.7, p=0.014) and 12 weeks (10.5 versus 2.1, p=0.001) after treatment. Total skin cancer index scores also increased from baseline to week 6 post-treatment (78.4 versus 89.0, p=0.001). Radiation dermatitis, skin pain and pruritus were the most common AEs, with all AEs resolving to grade ≤ 1 by 12 weeks post-treatment. Significant improvements were identified in QoL and resolution of moderate early AEs by 6 to 12 weeks post-treatment.

Comment: Brachytherapy usually involves placing radioactive sources either on or in cancer tissues, but there are now several electronic brachytherapy skin cancer devices that use miniaturised X-ray sources instead of radionucleotides, which means there is limited damage to adjacent tissues, a reduced dose to treating staff, no leakage when in the off state and no radioactive waste. Patients often elect to undergo this form of treatment in cosmetic areas like the face, especially the nose and it is important that the results are not only tolerable but also provide a good cosmetic effect. Using an Estaya ESSB device, patients in this trial received 6 fractions of X-ray brachytherapy over a 2-3-week treatment course and were assessed for adverse outcomes, cosmesis and QoL scores over the following 12 weeks. The peak time for adverse reactions was at 2 weeks when the radiation dermatitis was most obvious. but this improved rapidly, and at 12 weeks 94% of patients were very happy with the results. This compares favourably to surgery and should be considered in early-stage keratinocyte cancers in cosmetic areas.

Reference: Int J Radiat Oncol Biol Phys. 2023;1;116(3):544-550. Abstract

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CSCC=cutaneous squamous cell carcinoma; laCSCC=locally advanced CSCC; mCSCC=metastatic CSCC; ORR=objective response rate; SCC=squamous cell carcinoma.

References: 1. LIBTAYO (cemiplimab) Approved Product Information. 2. Cancer Council Australia Keratinocyte Cancer Guidelines Working Party. Clinical Practice Guidelines for Keratinocyte Cancer. Section 12.2: Systemic therapies for metastatic cutaneous squamous cell carcinoma. https://wiki.cancer.org.au/australia/Clinical_question:Protocol_to_treat_local_regional_SCC (accessed August 2023). 3. Australian Government, Department of Health and Aged Care. The Pharmaceutical Benefits Scheme. www.pbs.gov.au/pbs/home (accessed August 2023).



Sanofi and Regeneron are collaborating in the global development and commercialisation for LIBTAYO® (cemiplimab). ©2023 Sanofi-Aventis Australia Pty Ltd trading as Sanofi. ABN 31 008 558 807. 12–24 Talavera Road, Macquarie Park, NSW 2113, Australia. www.sanofi.com.au MAT-AU-2301819. Ward7 SALI30537M. Date of preparation: August 2023.

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Real-time, in vivo skin cancer triage by laser-induced plasma spectroscopy combined with a deep learning-based diagnostic algorithm

Authors: Pyun SH et al.

Summary: Researchers investigated the diagnostic accuracy of *in vivo* skin cancer diagnostics, using laser-induced plasma spectroscopy (LIPS) and a deep neutral network-based diagnostic algorithm. In a multisite clinical study, *in vivo* LIPS spectra acquired 296 skin cancers (186 basal cell carcinomas, 96 squamous call carcinomas, 14 melanomas) and 316 benign lesions. Using LIPS and deep neutral network-based algorithm, the sensitivity and accuracy for distinguishing skin cancers from benign lesions was 94.6% (95% CI 92.0 to 97.2) and 88.9% (85.5 to 92.4), respectively. There were no AEs or other visible marks or pigmentation from laser irradiation observed. This is a promising tool to aid in differing skin cancers from benign lesions, and to improve diagnostic accuracy within clinical settings.

Comment: Laser devices have recently been developed that can fire a nanosecond-length pulse into tissues and analyse the plume produced without damaging or changing the appearance of the lesion analysed. Elements such as magnesium, calcium, sodium, zinc and copper represent various processes occurring in the tissue and their levels differ between benign and cancerous material and this creates the basis for triaging benign skin lesions from malignant ones. Using machine learning and training data sets, the LIPS device performed *in vivo* analysis in dermatology and skin cancer clinics in Sydney and Newcastle, NSW. The lesions were excised, and the subsequent histology results were compared to the LIPS prediction; the overall sensitivity was high (94.6%) as well as good specificity (88.9%). Whether this will replace diagnosis via dermatoscopy, and skin biopsy may depend on the cost of the machine, but it offers an accurate and rapid method for diagnosing skin cancer as part of a routine skin check.

Reference: J Am Acad Dermatol. 2023;89(1):99-105. Abstract

Clinical and dermoscopic variation of basal cell carcinoma according to age of onset and anatomic location: a multicenter, retrospective study

Authors: Song Z et al.

Summary: Within this study, researchers investigated the dermoscopic variability of BCC, according to age. An Asian population was assessed, where clinical and dermoscopic features of 448 BCC's were compared based on their age of onset (age <50/>50 years) and their anatomic location. It was identified that early-onset BCCs were more common on non-sun-exposed sites (OR 3.28, p=0.001), and contained less pigmentation than late-onset BCC's (p=0.003). Factors associated with early-onset BBCs were blue-grey globules (OR 1.74, p=0.037) and no vessels (2.04, p=0.021), with telangiectasia (0.30, p<0.001), large blue-grey ovoid nests (0.38, p<0.001) and ulceration (0.33, p<0.001) being less common. Scalp BCCs had the most amount of pigmentation, compared to anywhere else (p=0.022). Factors linked to trunk BCCs were superficial subtype (5.90, p<0.001), spoke-wheel areas (4.78, p=0.034), superficial erosions (4.69, 0.001) and polymorph vessels (6.86, p=0.001), whereas nodular subtype (5.48, p<0.001) and arborising telangiectasias (3.64, p<0.001) were linked to face and neck BCCs. These findings suggest that age of onset and anatomic location can impact the dermoscopic appearance of BCC.

Comment: BCC is the most common malignancy worldwide and this study from China looked at the variation in location and dermoscopic features between "early-onset BCC's" – patients less than 50 years old – and "late-onset BCCs". In younger patients there were less likely to be arborising vessels and large pigmented nests, and there were more lesions in sun-protected areas like the trunk. The majority of lesions in this Asian population were pigmented BCCs, as would be expected, but the proportion of pigmented BCCs was lower in the younger group. They hypothesised that younger patients may have their BCCs diagnosed at an earlier stage before large nests and vascular features become apparent and may be more genetically susceptible due to poor DNA repair mechanisms and so develop more lesions without excessive sun exposure.

Reference: Arch Dermatol Res. 2023;315(6):1655-1664. Abstract

Evaluation of primary care physicians' competence in selective skin tumour triage after short versus long dermoscopy training: a randomized non-inferiority trial

Authors: Harkemanne E et al.

Summary: This study investigated whether a short dermoscopy e-learning course is non-inferior to a long course. Two-hundred and thirty-three primary care physicians (PCP), 126 GPs, 96 PCPs in training and 13 occupational physicians were included and randomly allocated to one of four groups. Fifty-eight received short training plus mandatory refreshers, 59 received short training plus optional refreshers, 58 had long training and mandatory refreshers, and 58 received long training plus optional refreshers for a duration of 8 months. Researchers evaluated PCPs' skills before training [T0], after training [T1] and 5 months post training [T2]. Amongst those included, 216 (93%) completed T1, with 197 (84.5%) completing T2. Within the per-protocol population, the primary endpoint for short versus long training was 1.392 (95% CI 0.138; 2.645, p<0.001), and was 1.016 (-0.224; 2.256, p<0.001) within the modified intention-to-treat population. Type of refresher had no impact on scores after training, however, those who did complete all refreshers obtained the best mean overall score at T2 (p<0.001). These results confirm that short training is non-inferior to long training, and that regular refreshers are of importance for maintaining PCPs' skills over time.

Comment: Short courses and simple algorithms have been shown to be effective methods for teaching GP's and trainee dermatologists how to distinguish benign from malignant skin lesions. A short course teaching the essentials of dermatoscopy was compared with a long, multi module course and there were groups with optional or compulsory refresher training. The short training performed as well as the longer training and refresher training improved diagnostic performance. It appears that a short course is an effective way to improve skin cancer management and has fewer barriers to participation such as time constraints and financial issues. The TADA algorithm was used here, but Chaos and Clues is another example of a very effective short course which most of us are very familiar with.

Reference: J Eur Acad Dermatol Venereol. 2023;37(8):1595-1605. Abstract

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RESEARCH REVIEW

Development and validation of a model to predict complex Mohs micrographic surgery in clinical practice: REGESMOSH scale

Authors: Montero-Vilchez T et al.

Summary: Researchers aimed to identify factors associated with a complex Mohs micrographic surgery (MMS), and to produce a predictor model for the number of stages needed within surgery. This was a nationwide prospective cohort study, including a total of 5.226 patients who had underwent MMS, and were in the REGESMOHS registry (4,402 [84%] had a histological diagnosis of BCC). There were 3,689 (88.9%) surgeries that required one or two stages, however there were 460 (11.1%) that required three or more. Models that were able to predict whether patients needed three or more stages were; tumour dimension, immunosuppression, recurrence, location in risk areas, histological aggressiveness as well as previous surgery. Majority of closure's required a complex closure (61.2%, n=2,552), with 1,616 (38.8%) requiring a non-complex closure. Researchers state that this model could be used to optimise surgery schedule and may properly inform patients about the duration of their surgery.

Comment: Mohs surgery can be time-consuming and the number of excision stages is hard to predict. Once the tumour has been cleared the resulting defect may be large and require complex surgery. Using data from Mohs centres in Spain, a model was developed to predict which patients were likely to require multiple excisions stages and complex repairs. The results are useful for non-Mohs excisions too because we can predict which patients need wider margins and which tumours should be allocated more time for complex closures. Larger tumour size, immunosuppression and recurrent tumours were the most important predictors for multiple excision stages and larger tumours, high risk sites and older age (>80 years) were the most important factors predicting complex closures.

Reference: J Eur Acad Dermatol Venereol. 2023:37(8):1587-1594. Abstract

Avelumab for the treatment of locally advanced or metastatic Merkel cell carcinoma—A multicenter real-world experience in Israel

Authors: Averbuch I et al.

Summary: In this study, researchers assessed real-world data of the effectiveness of avelumab in patients with Merkel cell carcinoma (MCC). Five electronic databases of university hospitals in Israel were analysed, identifying MCC patients who had received at least one dose of avelumab from 2018-2022. Sixty-two patients were included, of which 22% were immune suppressed. ORR for avelumab was 59%, with a median PFS of 8.1 months and OS of 23.5 months. Additionally, there were no differences identified between immune-competent and immune-suppressed patients. Overall, the treatment was well tolerated, with 34% of patients experiencing any-grade toxicity, and grade 3-4 toxicity occurring in 14%. Findings suggest that avelumab is an effective and safe treatment for advanced MCC, but that further studies are warranted to determine the optimal sequence and duration of treatment.

Comment: MCC is rare, but it's incidence is increasing and since it is a very aggressive tumour, early diagnosis and treatment is vital. Both pembrolizumab and the PD-L1 inhibitor avelumab have been shown to be effective in treating MCC and the latter drug is now licenced by the FDA for this indication. This paper in Israel identified 62 patients over a 4-year period, with a mean age of 74.5 years. Seventy percent of patients treated with avelumab benefited, with 37% achieving a CR, 22% a partial response and 11% stable disease. If patients recurred or had areas of tumour which failed to respond, these lesions could be treated with radiotherapy or surgery which prolonged the effectiveness of avelumab as far as overall and disease-free survival. Adverse effects were generally mild, which is important in this age group.

Reference: Cancer Med. 2023;12(11):12065-12070. Abstract

Combination oncolytic virus, radiation therapy, and immune checkpoint inhibitor treatment in anti-PD-1-refractory cancer

Authors: Jhawar SR et al.

Summary: Researchers aimed to determine whether the combination of oncolytic virus and radiotherapy will improve cancer outcomes. Vitro mouse and human cancer cell lines were utilised, and underwent both front-line treatments, with some receiving an immune checkpoint blockage. After analysis, it was found that oncolytic virus plus radiotherapy can reduce tumour growth, through the conversion of immunologically 'cold' tumours to 'hot' via a CD8+ T cell and IL-1a-dependent mechanism. Additionally, researchers described results of a PD-1-refractory patient with cutaneous squamous cell carcinoma, who received oncolytic virus, radiotherapy, and immune checkpoint inhibitor (ICI) therapy. This patient experienced unexpected, prolonged control and survival, and remains off-treatment with no progression for >44 months since he entered the study. These results provide a strong rationale for combining these three therapies for treatment in patients with ICI-refractory skin and potentially other cancers.

Comment: ICI therapy has revolutionised melanoma management and is also being used in a variety of other tumours, including cemiplimab for cutaneous squamous cell carcinoma. Unfortunately, there are some patients who fail to respond or cannot tolerate the AEs. Several other promising treatments are under investigation and combination therapy offers the opportunity to enhance therapy without additional immune-related adverse reactions. Radiotherapy is known to increase the expression of tumour antigens and inflammatory cytokines, and adding an oncolytic virus provides additional immunogenicity which makes response to ICI more likely. This paper reports a case of a 60-year-old man with cutaneous squamous cell carcinoma and lung metastases who relapsed after initially responding to the PD1 inhibitor cemiplimab. He was subsequently treated with a combination of nivolumab and an oncolytic herpes virus, but the skin tumour enlarged and so he received radiotherapy to the primary tumour site on his scalp. He then experienced a CR including distant pulmonary metastases -possibly due to the abscopal effect - and 44 months after the trial finished, he remained in remission. This case, and the studies subsequently performed in mouse models, suggests that it may be possible to rescue patients with disease progression using combination therapy.

Reference: J Immunother Cancer. 2023;11(7):e006780. Abstract



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