2025 AEDV Highlights

34ª edición
17-20 sep
PARÍS

Brilla el futuro de *la dermatologia*,
donde nace *la luz*

# Dermatología Oncológica y Cirugía


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ACADEMIA ESPAÑOLA DE DERMATOLOGÍA Y VENEREOLOGÍA

FUNDACIÓN AEDV PIEL SANA

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## SÍ TENGO CONFLICTOS DE INTERÉS

Pierre-Fabre

Masderm

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# Melanoma

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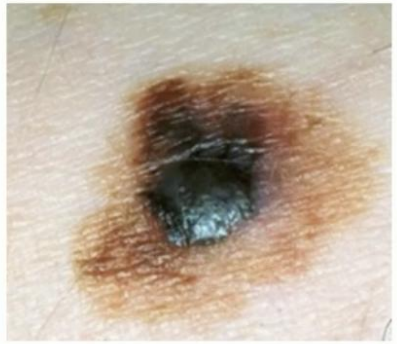
# Melanoma

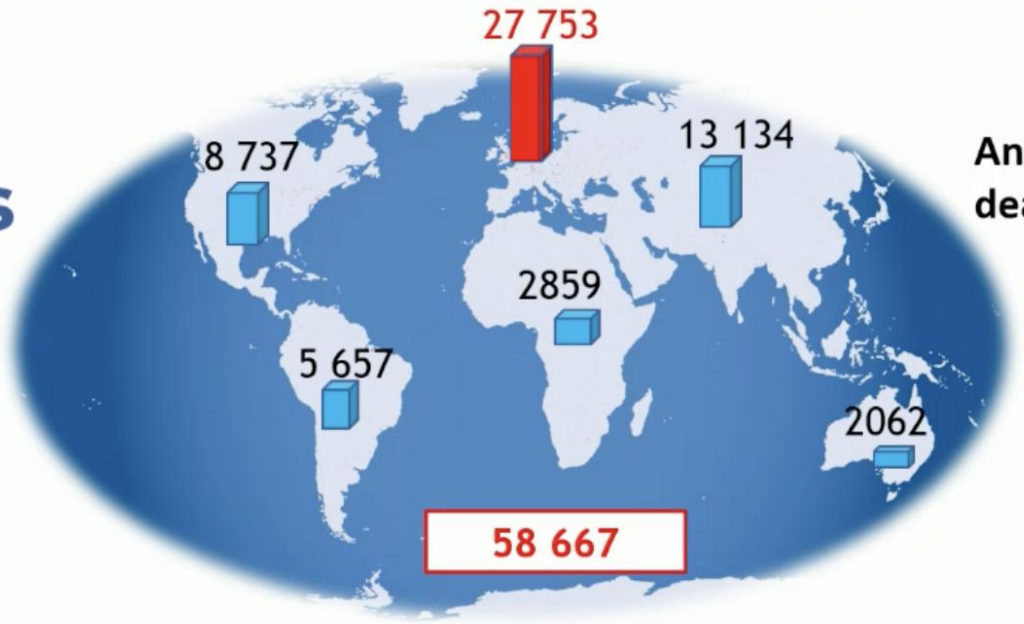


Slides by Dr. Ana Maria Forsea

EADV CONGRESS

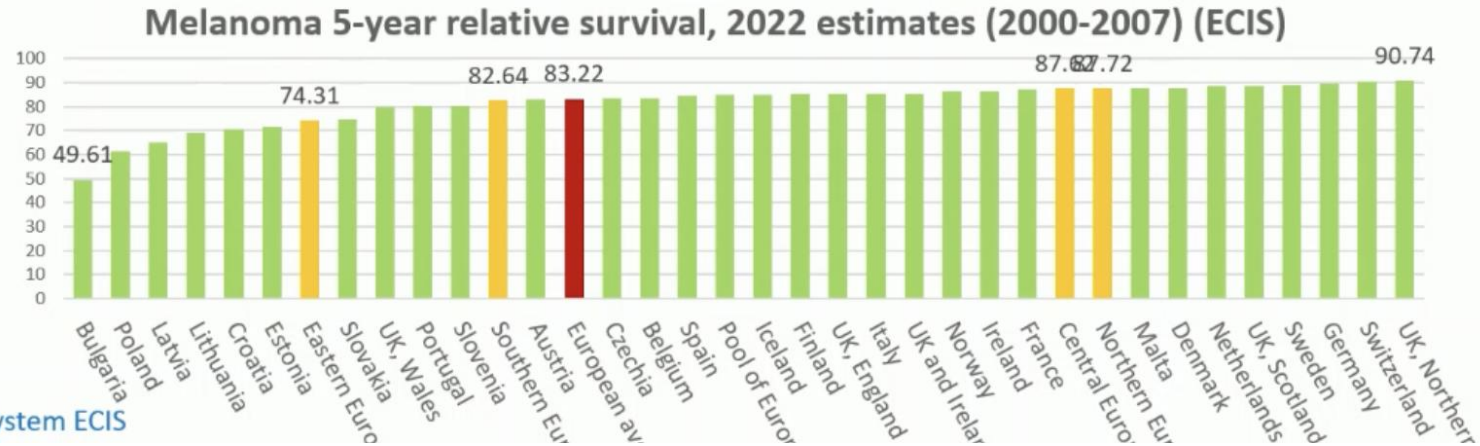
## Melanoma kills






**Annual melanoma deaths world-wide**

Data source: Global Cancer Observatory 2022 (IARC)



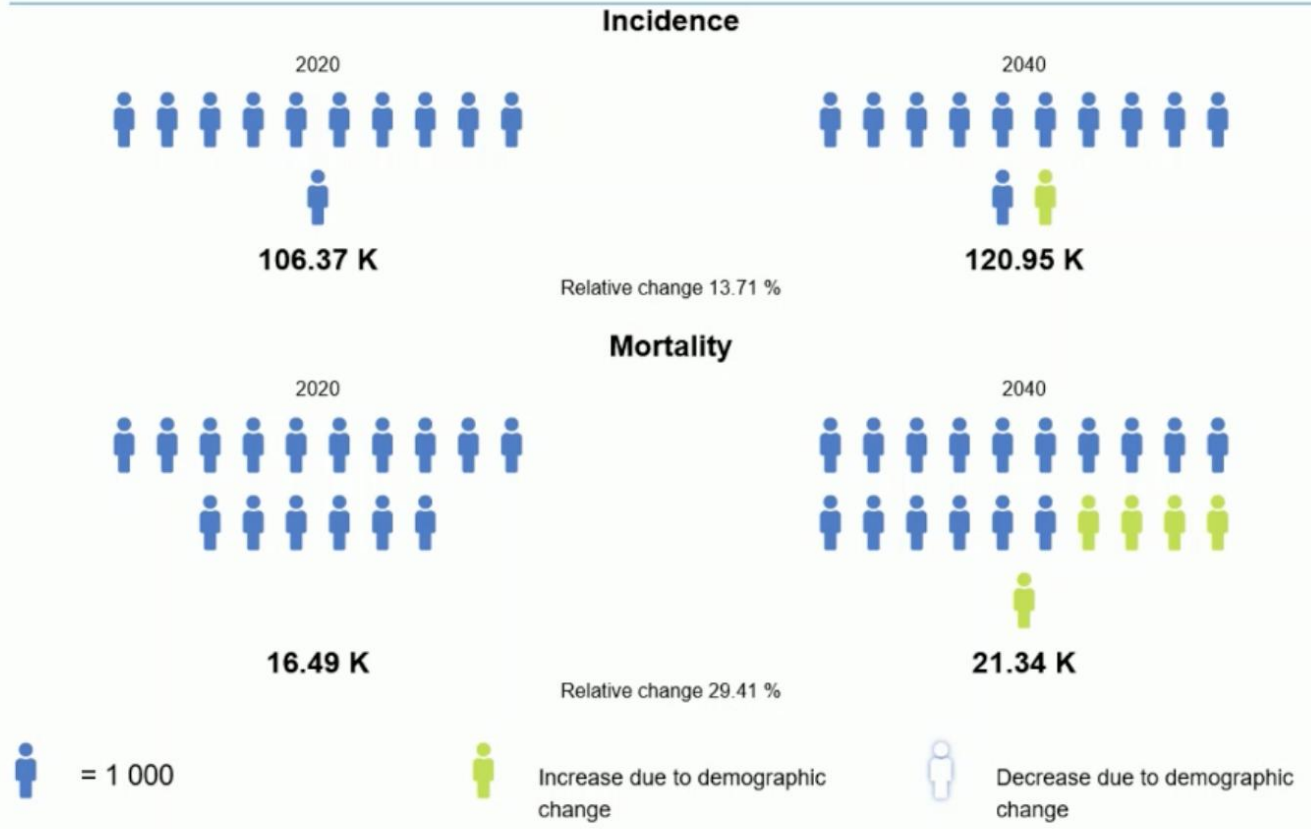

Data source: European cancer Information System ECIS

# Melanoma



EADV CONGRESS

## Melanoma future trends in Europe




Source: European Cancer Information System

Slides by Dr. Ana Maria Forsea

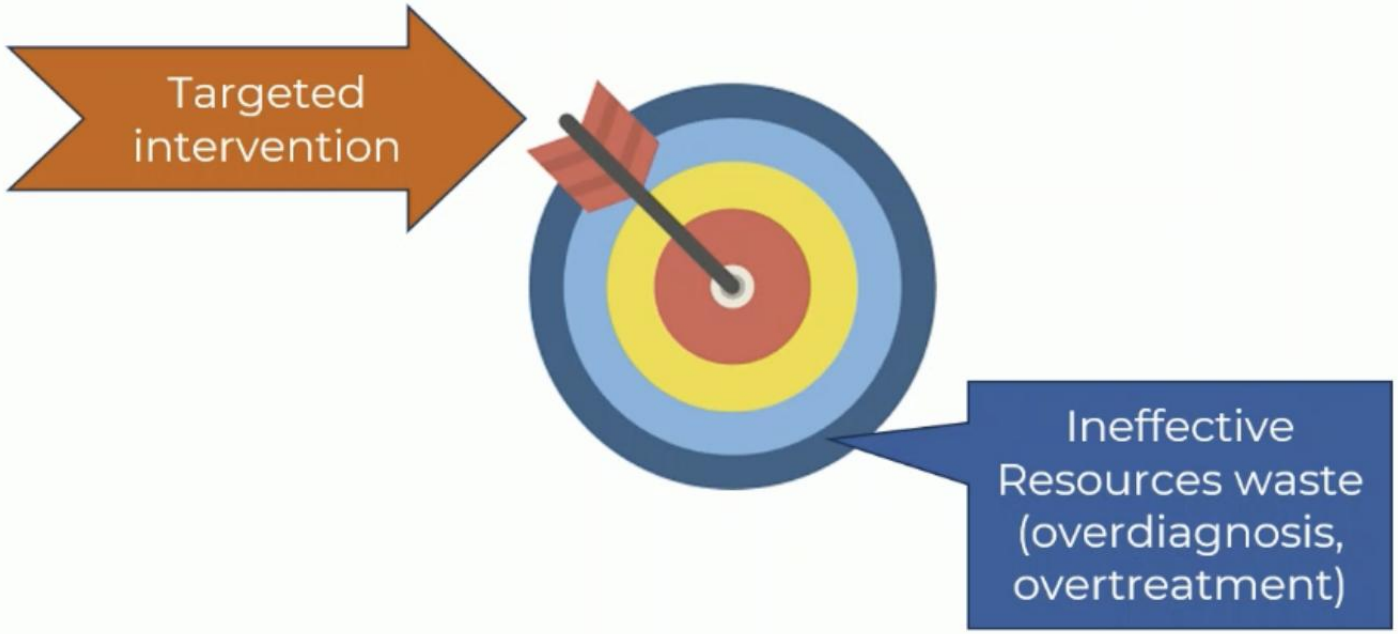
# Melanoma

EADV CONGRESS

## Decrease melanoma burden

Primary prevention

Early detection



# Melanoma

Prevención primaria: campañas educativas (Euromelanoma)

Detección precoz:

- Screening poblacional – no es efectivo / eficiente / evidencia
- Dirigido a grupos de alto riesgo

**Non modifiable (Risk markers)**

Multiple nevi phenotype

Atypical nevi

Phototype ( I/II, blond/red hair, blue/green eyes, freckling)

Family history

Medical history (melanoma, immunosuppression, cancers, a.o.)

Genotype (CDKN2A variants, MITF variants, MC1R variants, TP53 variants, CDK4 variant, TERT mutations)

**Modifiable Risk factors**

- UV exposure

natural/artificial, professional/ recreational, intermittent/ chronic, sunburns

# Melanoma – Grupos de alto riesgo

| High risk (RR 1-4x) | Very high risk (RR >4x) |
|---|---|
| Multiple nevi (50-100) | > 100 nevi (RR 6.89) |
| Atypical nevi | > 5 atypical nevi (RR 6.36) |
| I$^{st}$ degree family history (1 case) | I$^{st}$ degree family history (>2-3 cases) |
| Phototype I, II | CDKN2A mutation carriers |
| Red/blonde hair | |
| Freckles | Giant congenital nevi>20cm |
| Organ transplant/immunosuppression | Personal melanoma history (RR 8.57) |
| Solar damage (3x) | |
| History of excessive sun exposure | |
| Non-melanoma skin cancer history (personal/family) | |
| Other cancers | |

*Multiplicative effect of cumulative risk factors

P Bradford et al, Arch Dermatol. 2010 ; Caini et al, EJC 2005; Watts et al, Brit J Derm 2015

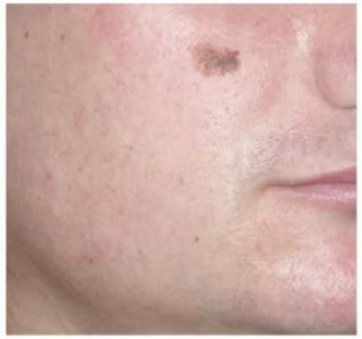
Slides by Dr. Ana Maria Forsea

# Melanoma – Grupos de alto riesgo

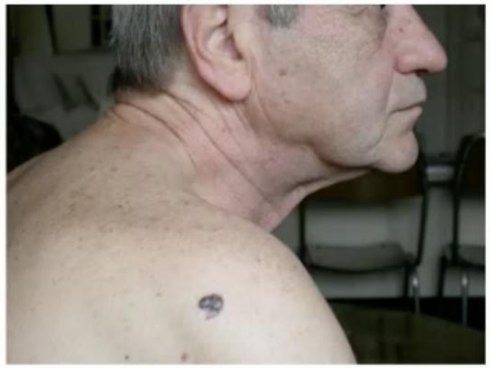
- Melanomas altamente agresivos

Slides by Dr. Ana Maria Forsea

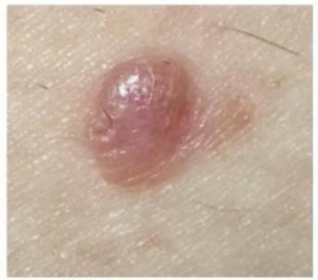
**Risk of getting a melanoma** ≠ **Risk of dying of melanoma**



- Male sex, >50y old
- Highest melanoma incidence, incidence increase, thickness at diagnosis; Lowest stage-adjusted survival
- Living alone
- Low socio-economic status



- Fast growing/ nodular melanoma (NMM)
  - NMM: 14% of all melanomas, 40% of melanoma deaths
  - **EGF** (Elevated, Firm, Growing rapidly)
- Immunosuppression

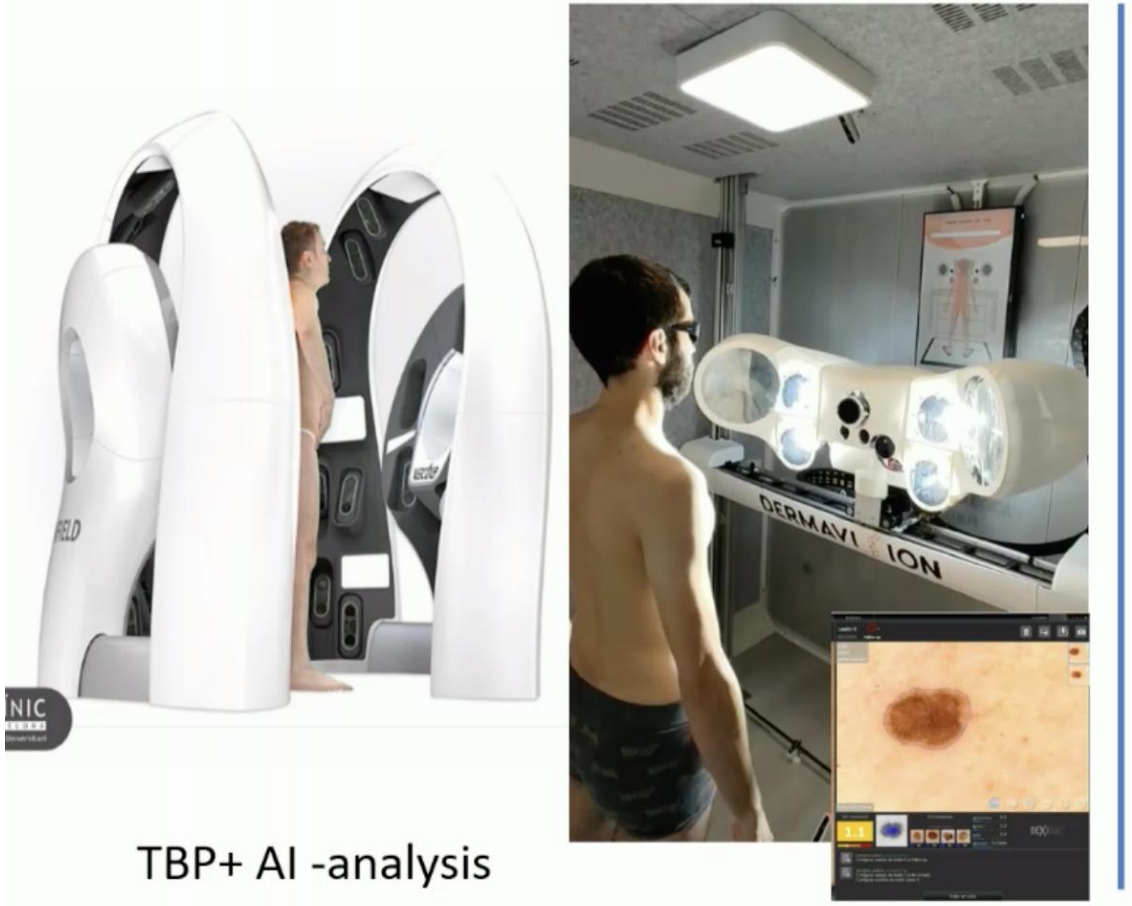


High-risk targeted screening: Selection criteria/threshold ? Method of triage?

# Melanoma – Grupos de alto riesgo

- Futuro

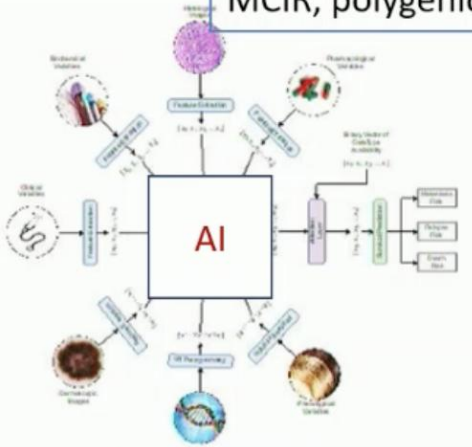
## Deep imaging




TBP+ AI -analysis

„DEEP IMAGING“
(total body photography+ dermatoscopy)

GENETICs
CDKN2A, G101w, MITFwt, POT-1, TERT, MCIR, polygenic scores




CLINICAL
Personal medical, familial, medicatio, exposure history

DEMOGRAPHICS
Age, sex, ethnicity phototype, sun exposure, geography,

Kahler SKINdeep 1: e150261 (2025) DOI: 10.1553/skindeep.2025.150261

# Melanoma – Ganglio Centinela Si o No?

- Valor pronóstico
  - Determina el seguimiento con pruebas de imagen
  - Candidatos a tratamiento adyuvante
- Efecto terapéutico limitado a control regional de la enfermedad
- Efectos adversos: linfedema (5%)
- Cambio de paradigma 2021 – 2023: antiPD1 estadios IIB/IIC indep del GC

# Melanoma – Ganglio Centinela Si o No?

- Ganglio Centinela SI: estadios IB y IIA (candidatos a tto adyuvante)

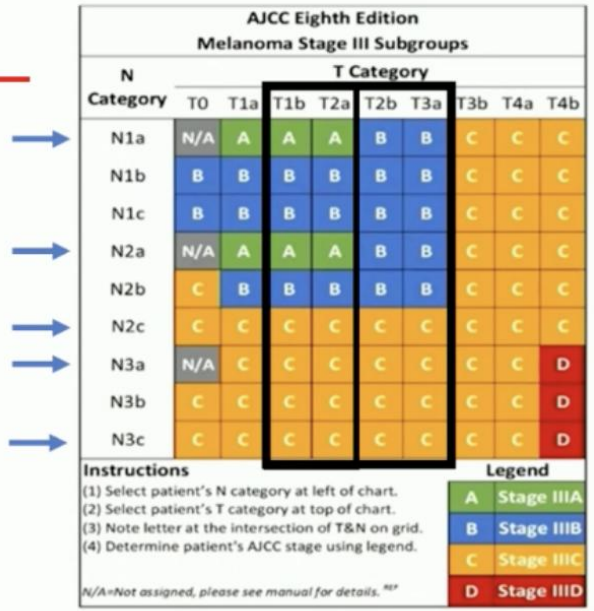
Slides by Dr. Eduardo Nagore

## What about clinical stages IB and IIA?

| Clinical stage | Contributing T categories | Typical SLN+ range |
|---|---|---|
| ~~IA~~ | ~~T1a (<0.8 mm, no ulceration)~~ | ~~<5%~~ |
| IB | T1b or T2a | ≈5–11% (5% T1b; ~11% T2a) |
| IIA | T2b or T3a | ≈10–20% |
| IIB | T3b or T4a | ≈25–35% |
| IIC | T4b (>4 mm, ulcerated) | ≈35–45% |

**SLN status can:**

- **Modify follow-up**
- **Indicate adjuvant therapy**

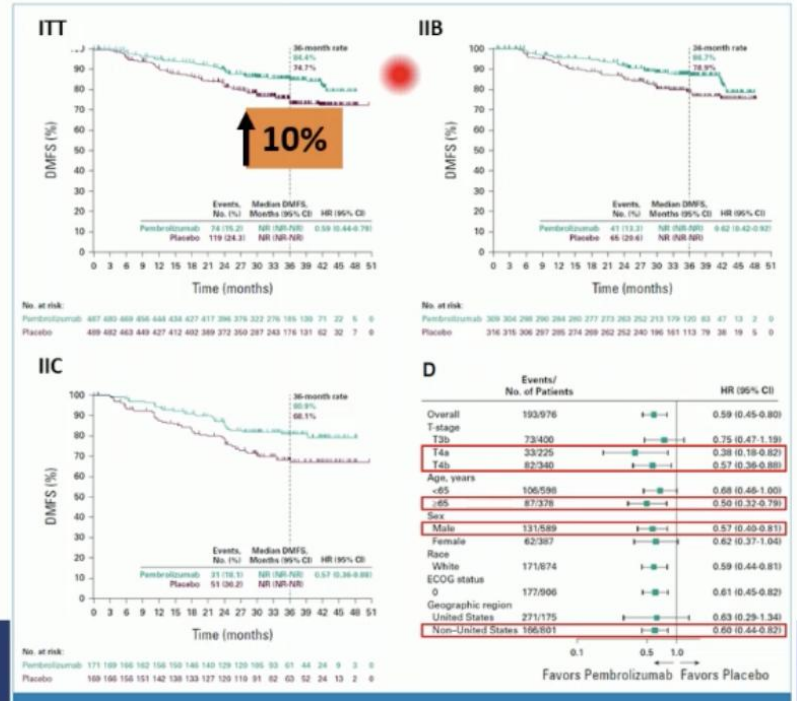


# Melanoma – Ganglio Centinela Si o No?

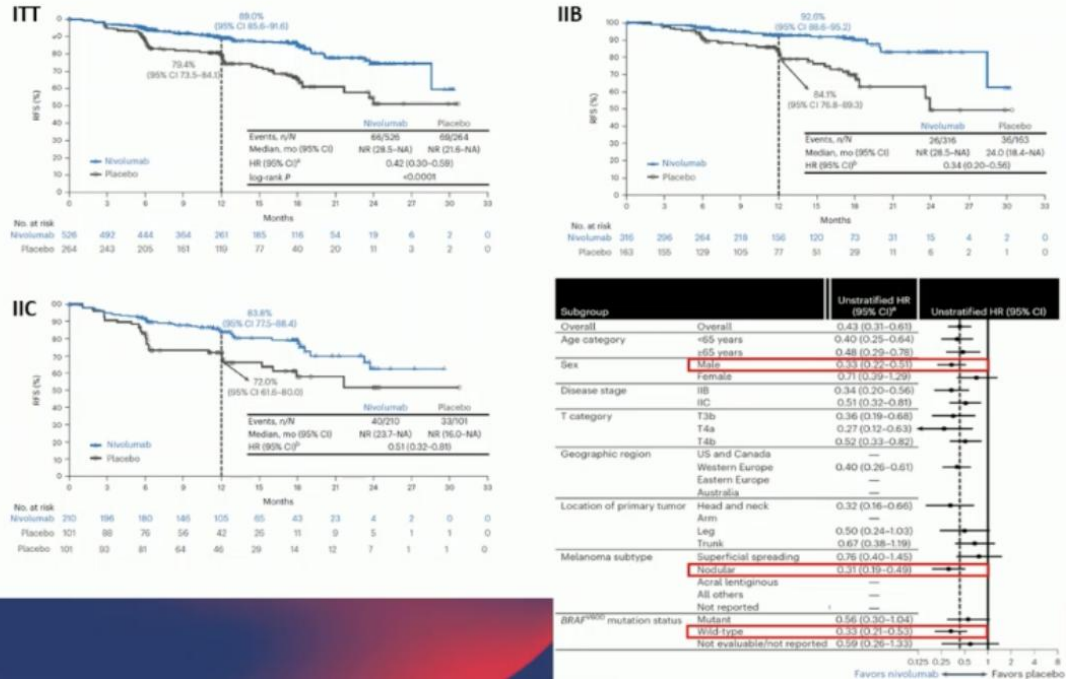
Slides by Dr. Eduardo Nagore

## Clinical trials demonstrating the value of adjuvant therapy in stages IIB and IIC

**Pembrolizumab Versus Placebo as Adjuvant Therapy in Resected Stage IIB or IIC Melanoma: Final Analysis of Distant Metastasis-Free Survival in the Phase III KEYNOTE-716 Study** JCO 2024




**Adjuvant nivolumab in resected stage IIB/C melanoma: primary results from the randomized, phase 3 CheckMate 76K trial** Nat Med 2023



# Melanoma – Ganglio Centinela Si o No?

- Ganglio Centinela NO: estadios IIB/C
  - Ahorra efectos secundarios de la BSGC
  - ‘Neoadyuvancia’
  - Pero:
    - Coste y efectos secundarios
    - No ahorra adyuvancia
    - Equilibrio entre NNT y NND
    - Pronóstico incierto

Sin validación pronóstica!

## Limitations of current non-invasive predictive models

| Tool/Model; | AUC | Sensitivity | Specificity | PPV | NPV |
|---|---|---|---|---|---|
| MIA Nomogram | 0.69–0.75 | ~80–85% | ~40–50% | 15–23% | 90–95% |
| MSKCC Nomogram | 0.69–0.75 | ~80–85% | ~40–50% | 15–23% | 90–95% |
| CP-GEP/Merlin Assay | 0.72–0.74 | ~85–90% | ~40–50% | 18–20% | 91–94% |
| i31-GEP-SLNB | ~0.72 | ~85–90% | ~40–50% | 4–13% | >95% |

Slides by Dr. Eduardo Nagore

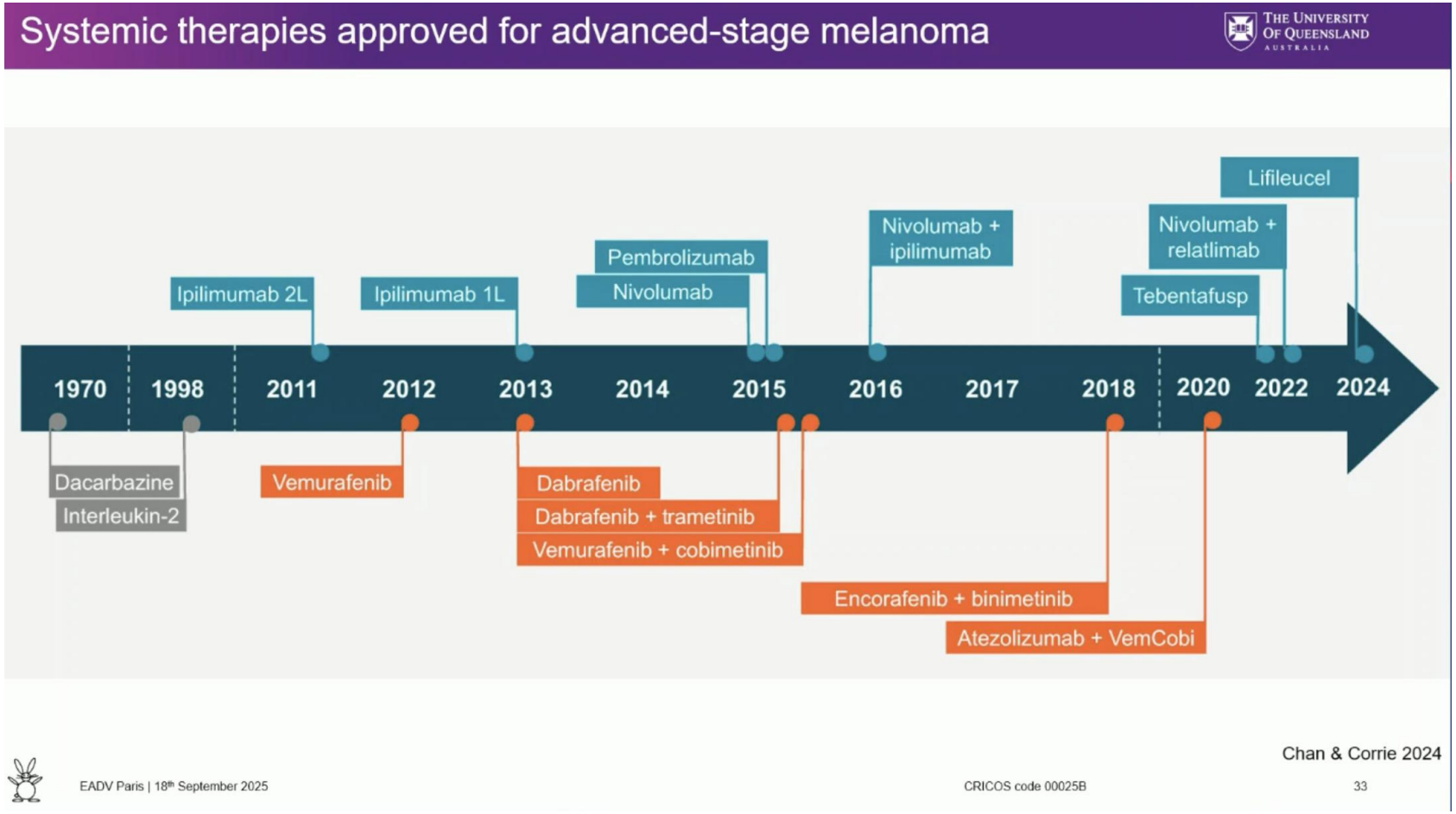
JCO 2020:2719; JAMA Surg 2024:260; Surgery 2024:1143; BJD 2021:412; J Surg Oncol 2025

# Melanoma – Inmunoterapia y Terapias Dirigidas



Slides by Dr. Haas

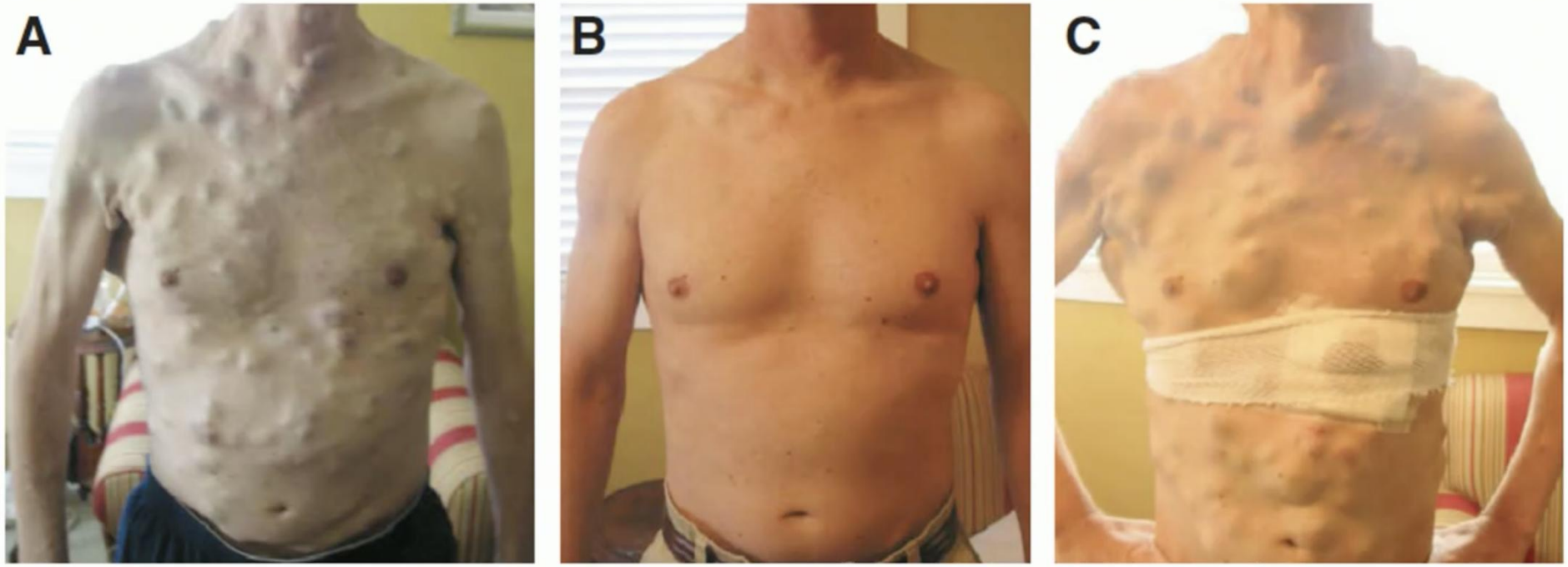
- 2011 – cambio de paradigma



# Melanoma – Inmunoterapia y Terapias Dirigidas

Slides by Dr. Haas

## Modern targeted melanoma therapies are highly effective – but not permanently



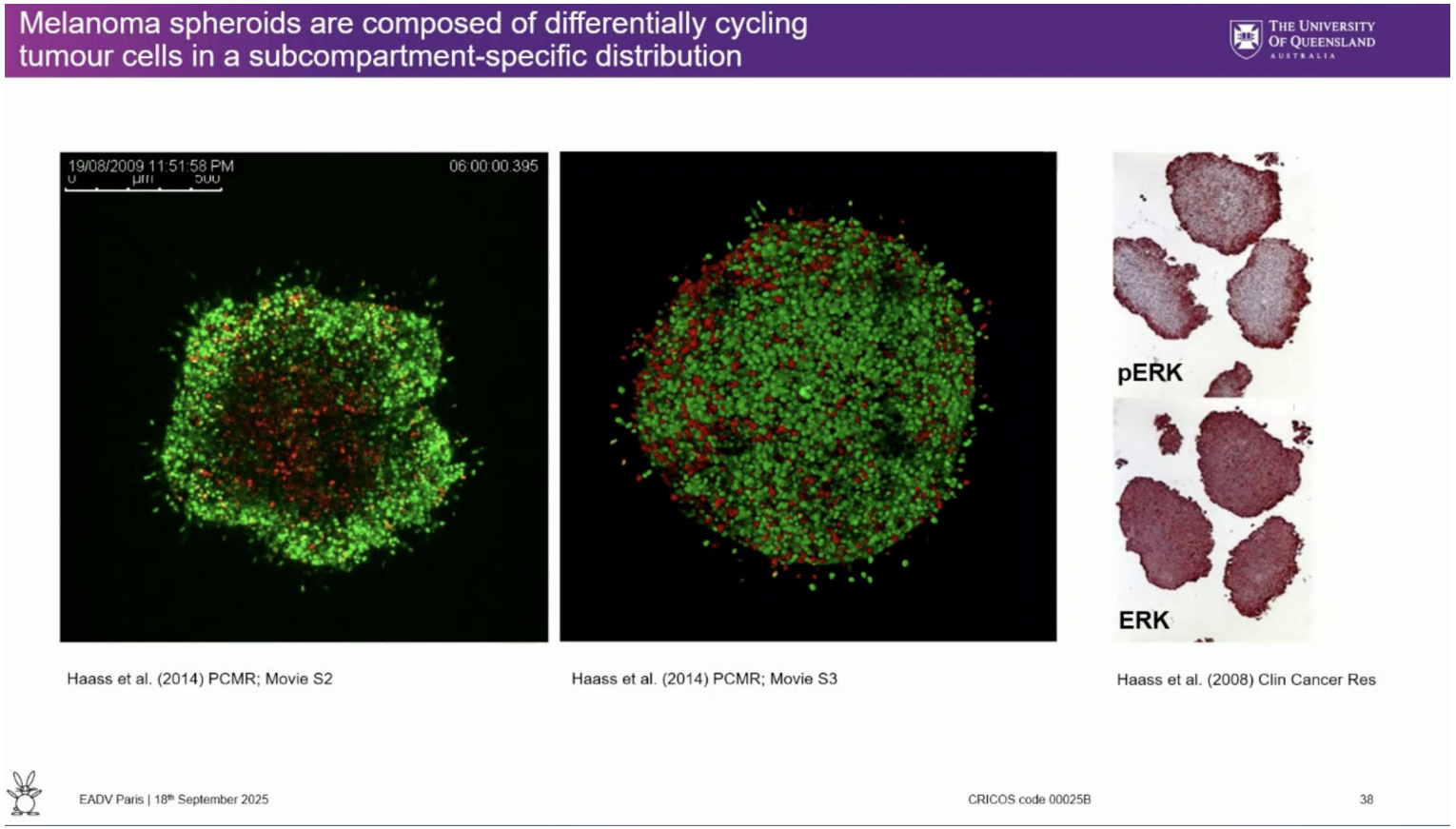

We believe that tumour heterogeneity may be partly responsible for this dilemma.

Wagle et al. (2011) *J Clin Oncol*

# Melanoma – Inmunoterapia y Terapias Dirigidas

Slides by Dr. Haas

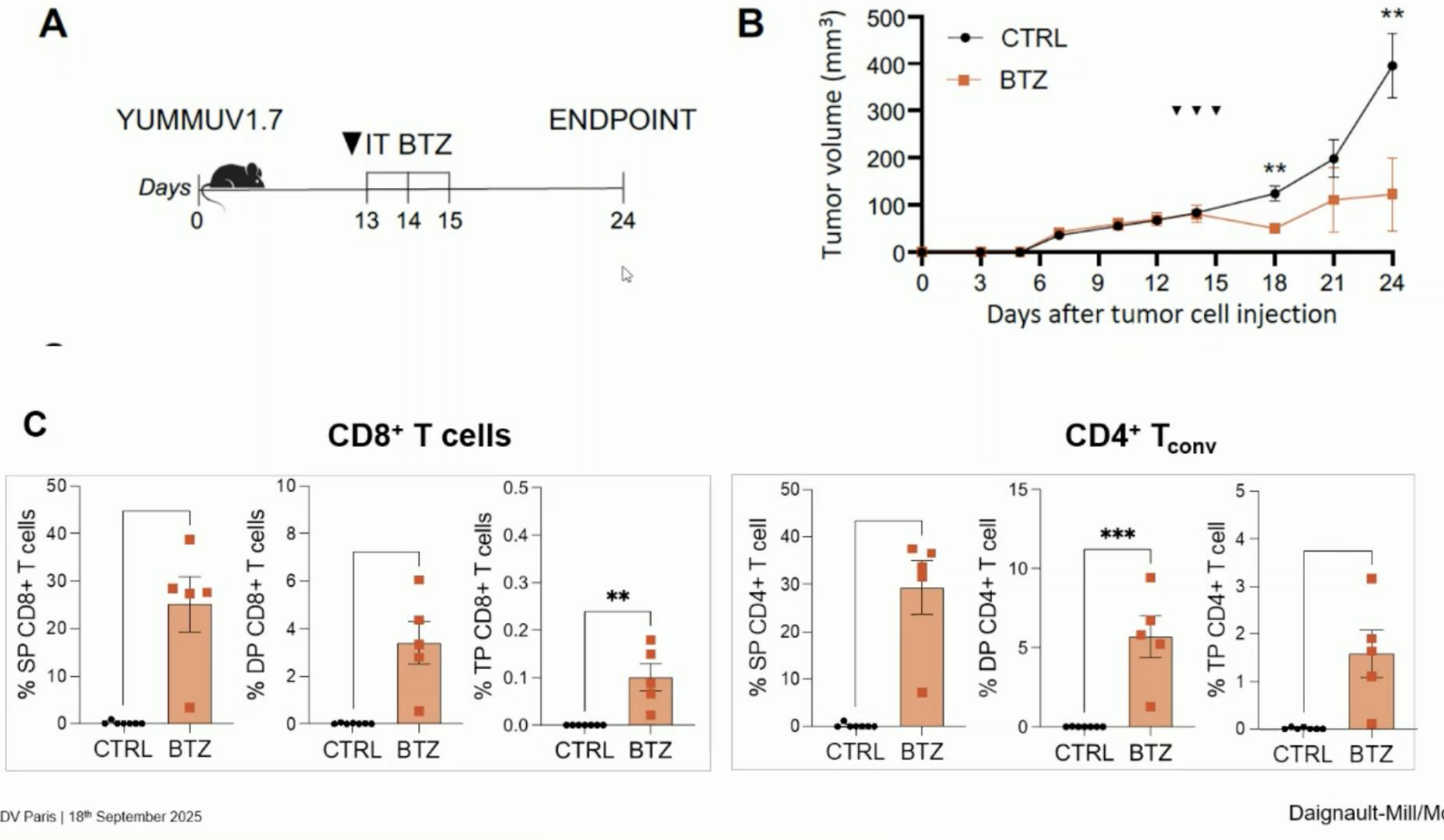
- Asociación de fármacos que mejoran la respuesta
  - ROCK (terapias dirigidas)
  - Bortezomib (inmunoterapia)



# Melanoma – Inmunoterapia y Terapias Dirigidas

Slides by Dr. Haas

## Intra-tumoural injection of BTZ generates tumour-specific T-cell response



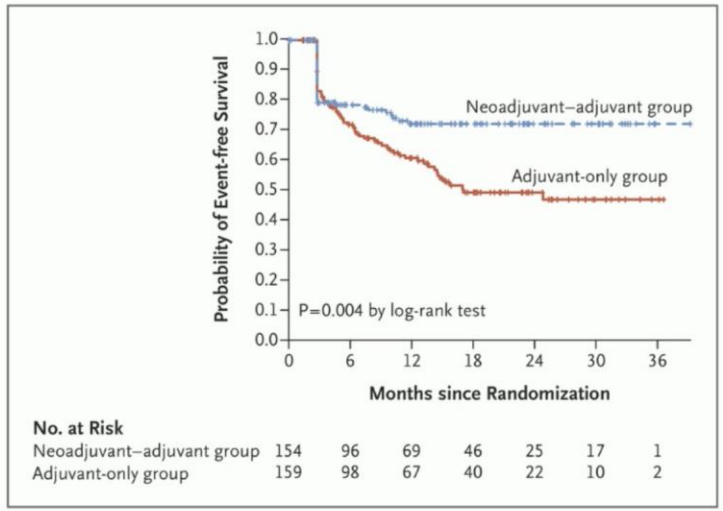

EADV Paris | 18th September 2025

Daignault-Mill/Moi et al. *in prep*

# Melanoma – Neoadyuvancia

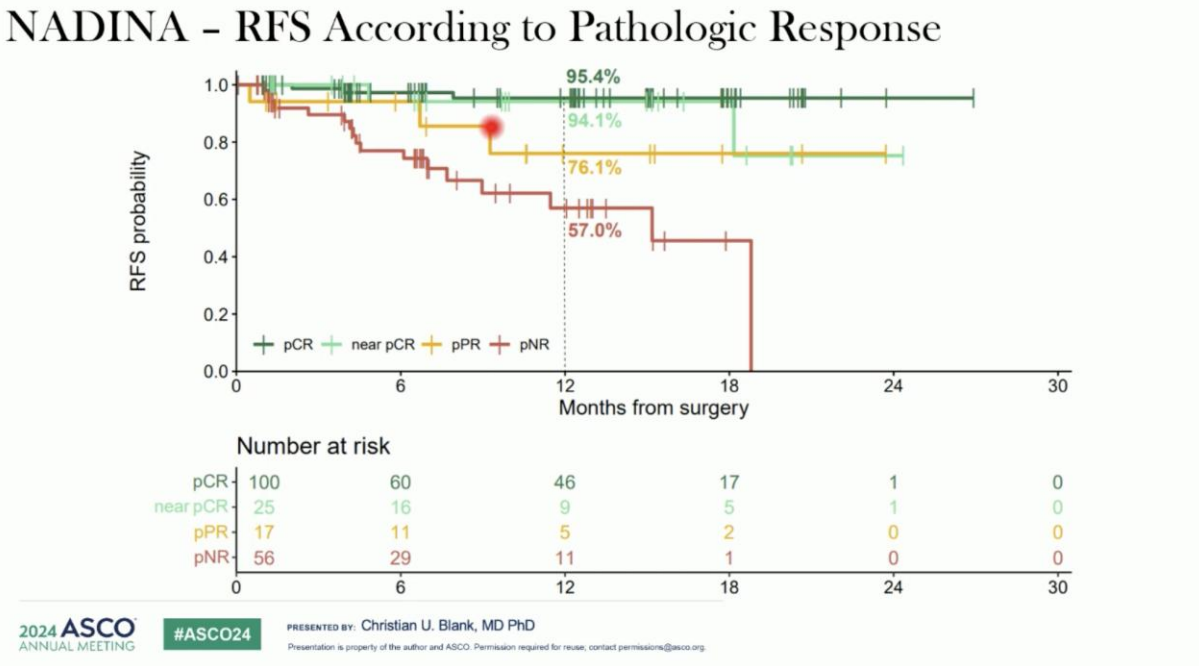
- Mejor supervivencia libre de enfermedad
- Similares EA

Slides by Dr. Ribero



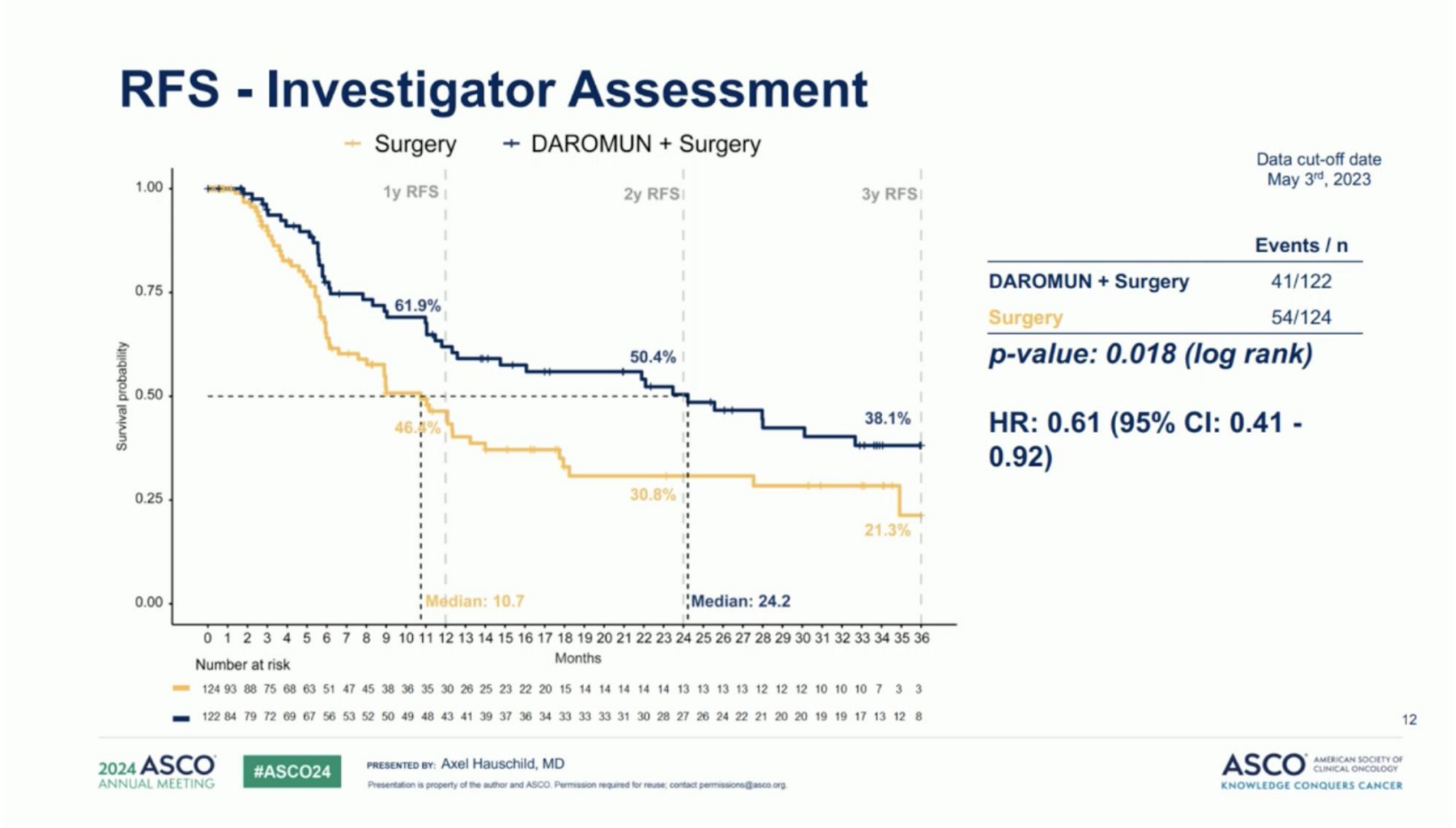

Median follow-up of 14.7 months.
Patel SP, et al. *N Engl J Med.* 2023;388(9):813-823.

- **2-year EFS**
  - Neoadjuvant-adjuvant: 72%
  - Adjuvant-only group: 49%
- **Adverse Events**
  - Similar rates of grade 3 or higher adverse events
  - No new toxic effects observed
- **Conclusion**
  - Timing of therapy (neoadjuvant vs adjuvant) was the only difference.
  - Neoadjuvant therapy showed a clear benefit



# Melanoma – Neoadyuvancia

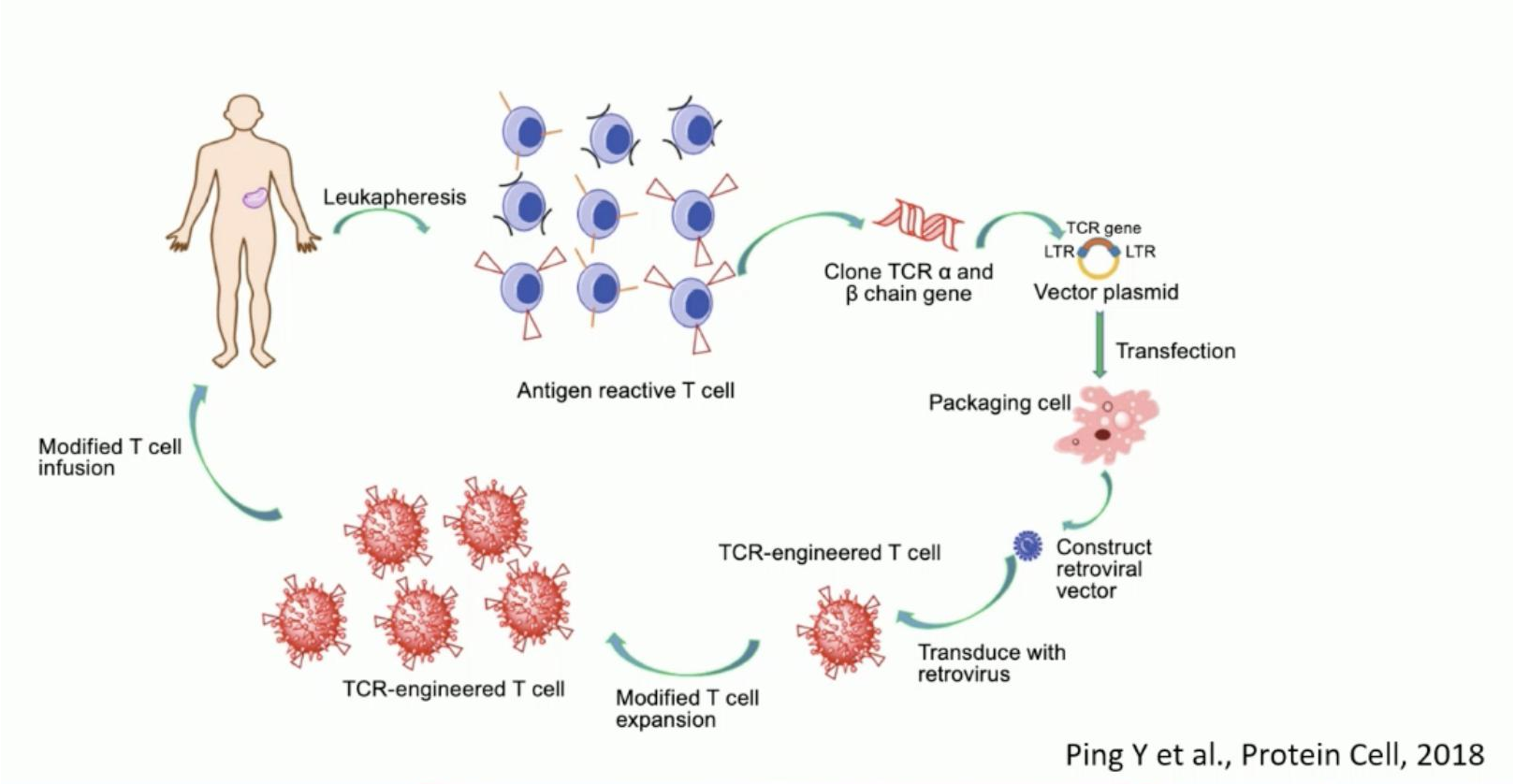
- Futuros fármacos: Daromun



# Melanoma – Terapia Celular

- TILs
- Células T modificadas
- CAR-T

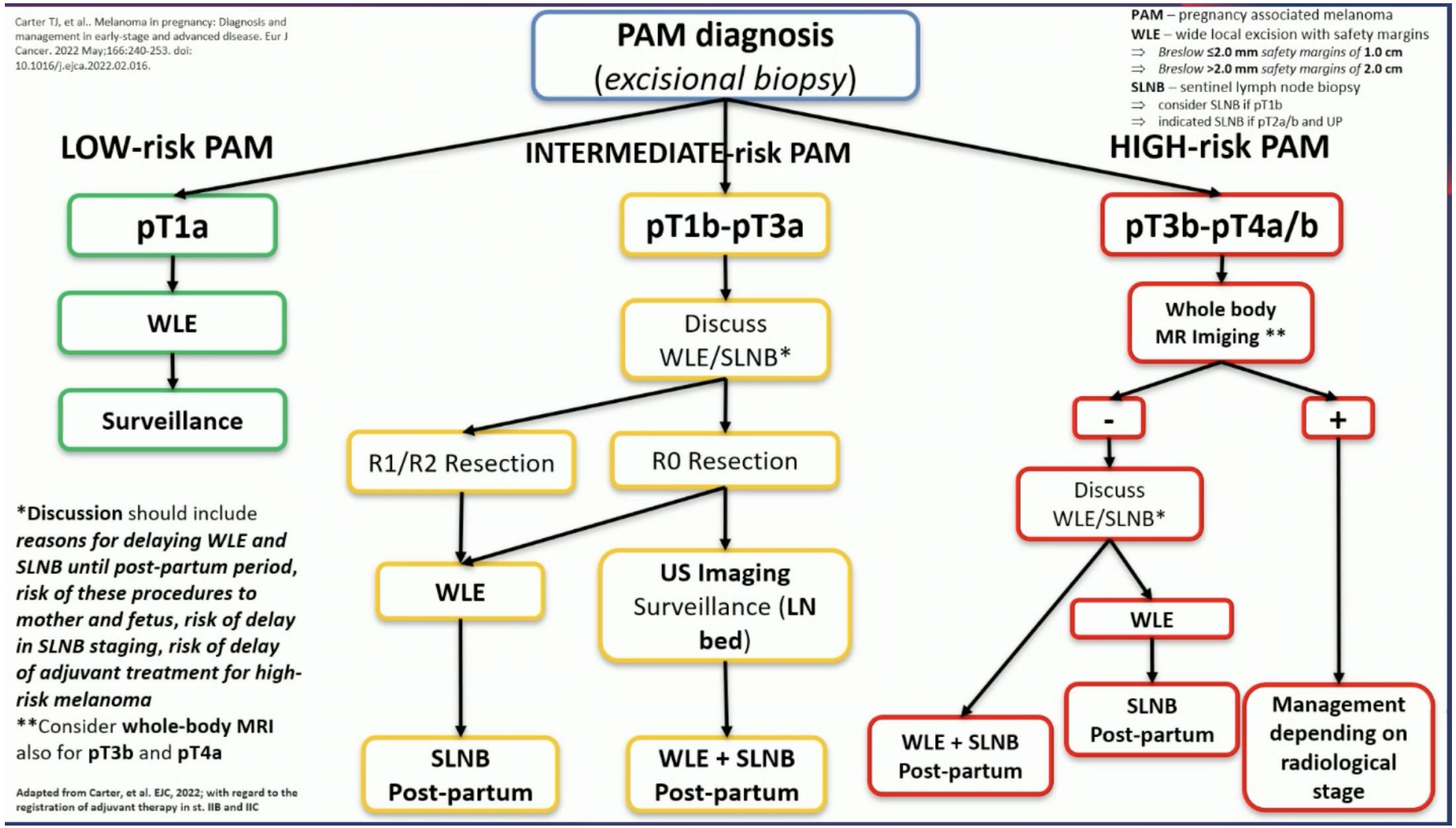
Slides by Dr. Flatz




Ping Y et al., Protein Cell, 2018

# Melanoma y embarazo

Slides by Dr. Pasek




# Carcinoma basocelular

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# CBC y exposoma



Slides by Dr. Nuno Gonzalez

EADV CONGRESS

International Journal of Dermatology

Report

**Exposome and basal cell carcinoma: a multicenter case–control study**

Alba Navarro-Bielsa,[1] Tamara Gracia-Cazaña,[1] Manuel Almagro,[2] Sonia De-la-Fuente-Meira,[3] Ángeles Florez,[4] Oriol Yélamos,[5] Trinidad Montero-Vilchez,[6] Carlos González-Cruz,[7] Adrián Diago,[1] Isabel Abadías-Granado,[8] Victoria Fuentelsaz,[9] María Colmenero,[10] Jose Bañuls,[11] Salvador Arias-Santiago,[6] Agustín Buendía-Eisman,[12] Manuel Almenara-Blasco,[1] Pedro Gil-Pallares,[13] and Yolanda Gilaberte,[1]

Navarro-Bielsa A, Gracia-Cazaña T, Almagro M, De-la-Fuente-Meira S, Florez Á, Yélamos O, Montero-Vilchez T, González-Cruz C, Diago A, Abadías-Granado I, Fuentelsaz V, Colmenero M, Bañuls J, Arias-Santiago S, Buendía-Eisman A, Almenara-Blasco M, Gil-Pallares P, Gilaberte Y. Exposome and basal cell carcinoma: a multicenter case-control study. Int J Dermatol. 2024 Jul;63(7):907-915

**Table 5** Logistic regression findings: variables significantly associated with the presence of BCC

| Variable | Coefficient | *P*-value |
|---|---|---|
| Hair color | 0.09745 | 0.004 |
| Phototype | 0.05610 | 0.021 |
| Current workplace (indoors) | −0.30581 | 0.011 |
| Previous outdoor work | 0.24359 | 0.013 |
| Daily hours of sun exposure | 0.06631 | 0.042 |
| Years of sun exposure | 0.01301 | 0.006 |
| Use of a hat or cap | 0.04960 | 0.038 |
| Higher exposure to ultraviolet radiation 15 years ago | 0.21638 | 0.003 |
| Relaxation activities | −0.19181 | 0.025 |
| Screen time | −0.13829 | <0.001 |
| Acetylsalicylic acid | 0.38249 | 0.046 |
| Statins | 0.18100 | 0.028 |
| Hydrochlorothiazide | 0.40734 | 0.002 |
| ACE inhibitors (captopril, enalapril, ramipril) | 0.33378 | <0.001 |
| Omeprazole | 0.17172 | 0.032 |
| Linolenic acid | 0.06926 | 0.022 |
| Coffee | −0.02525 | 0.059 |

ACE, angiotensin-converting enzyme.

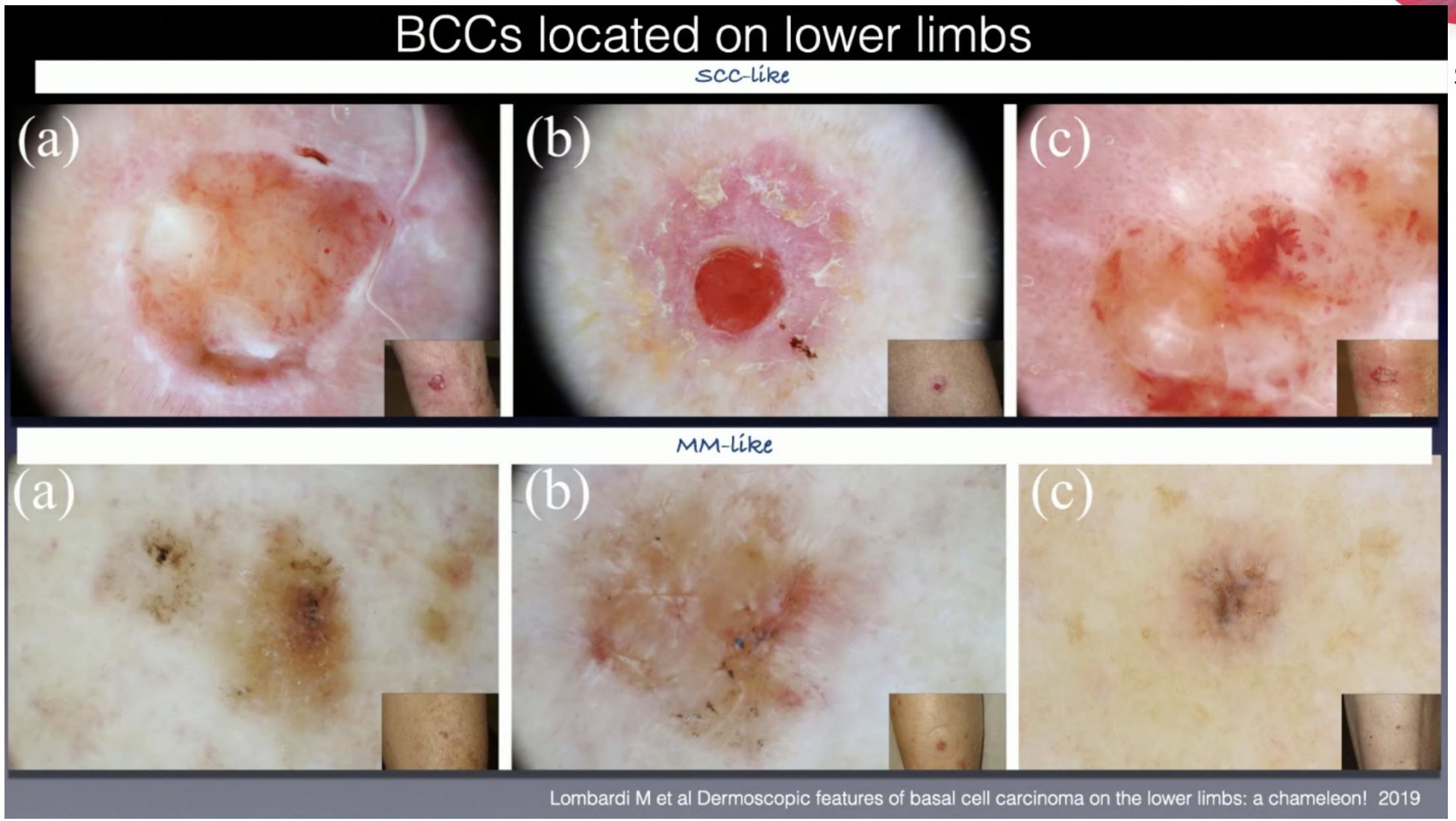
# CBC y exposoma

Slides by Dr. Nuno Gonzalez

## Diet and BCC

- Dietary Antioxidants: Vitamins A, C, E, selenium, nicotinamide may reduce UV-induced DNA damage
- Evidence is conflicting; some studies show increased cancer risk with supplementation, especially in high doses or specific populations
- Furocoumarins: Higher intake linked to increased BCC risk.
- Caffeine: Consumption (especially caffeinated coffee) shows a protective effect against BCC development; higher intake = lower risk.
- Best advice: prioritize a varied diet high in vegetables, limit alcohol, avoid excess citrus if heavy sun exposure

# CBC – Imagen

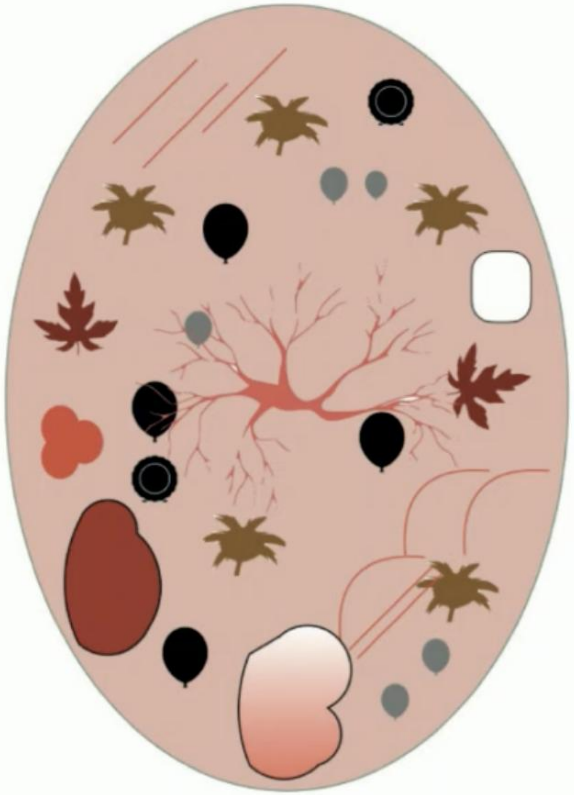



Slides by Dr. Longo

# CBC - Imagen

Slides by Dr. Longo

## BCCs and PDT response



| | Dermoscopy Structure | Response to PDT |
|---|---|---|
| | Bright white structures | Not associated |
| | Reddish-white areas structures | Not associated |
| | Ulceration | Not associated |
| | Multiple erosions | Not associated |
| | Linear and short telangiectasias | Not associated |
| | Leaf-like structures | Resistance |
| | Arborising telangiectasias | Not associated |
| | Specks of brown and grey pigment | Not associated |
| | Globules | Not associated |
| | Spoke wheel areas | Recurrence |
| | Concentric structures | Recurrence |
| | Blue ovoid nests | Recurrence |

DEPTH (- → +)

**Fig. 1. Dermoscopic structures associated with basal cell carcinoma (BCC) and the response to photodynamic therapy (PDT).**

Navarro Bilesa et al. ActaDv 2023

# CBC – tratamientos no invasivos

Slides by Dr. Bower

**Basal Cell Carcinoma: A Narrative Review on Contemporary Diagnosis and Management**
Oncol Ther
. 2022 Jun 21;10(2):317–335.
Naik P, Desai M

| Topical therapy | Nodular BCC | | Superficial BCC | |
|---|---|---|---|---|
| | Evidence | Efficacy | Evidence | Efficacy |
| 5 FU | IV | - | II | 68.2% 3-year CC |
| Retinoids | IV | - | IV | 58.5% PT CC |
| BEC -5 | II | 66% PT CC | II | 66% PT CC |
| Dobesilatey | IV | - | IV | - |
| Imiquimod | II | 76% PT CC | I | 78-80% 5-year CC |

CC Clinical clearance PT Post-treatment

# CBC – tratamientos no invasivos

AEDV Highlights 2025 — 34ª edición 17-20 sep PARÍS

Slides by Dr. Bower

## Intralesional therapy in BCC

| | Efficacy | |
|---|---|---|
| Interferon | 50-80%<br>3x/week 3-6 weeks | Used infrequently – cost; side effects; logistics |
| Methotrexate | Regression in large inoperable BCCs | Local inflammation; small studies |
| 5-FU | Regression in superficial/nodular BCCs – 70-90% | Small series; repeated injections |
| Bleomycin | Partial/complete regression in resistant BCCs | Low level evidence; Pain; local necrosis |
| Electrochemotherapy | Emerging standardised approach with promising local control | Tissue sparing palliative control |
| Oncolytic viruses (TVEC, RP1) | 50% (9/18) resectable after 6 cycles<br>Ressleret al Nature Cancer 2025 6,51-66 | Injection reactions; flu-like symptoms; promising area at early phase |
| Check point inhibitors | 44% response rate (systemic) in advanced BCC | Case reports and early-phase cohorts |

# CBC – tratamientos no invasivos

Slides by Dr. Bower

British Journal of Dermatology

Editorial

## Management of skin cancer in the frail elderly: time for a rethink?

J.K. Schofield, E. Linos, J. Callander


View issue TOC
Volume 175, Issue 5
November 2016
Pages 855–856

- Shared decision-making
- Underpinned by holistic patient-centred approach

**Royal College of Surgeons 2018**

- Take patient through every optior
- Let patients decide for themselves - since 2008, General Medical Council rules have stated that doctors should not make assumptions about the information a patient might need
- Doubling of average patient consultation duration

Lubeek et al

**Improving the applicability of guidelines on nonmelanoma skin cancer in frail older adults: a multidisciplinary expert consensus and systematic review of current guidelines†**

**My personal approach**

- Improve 'well-being'
  - Currently bothersome
  - Will become bothersome
- Avoid 'one size fits all'
- Treat patients not tumours

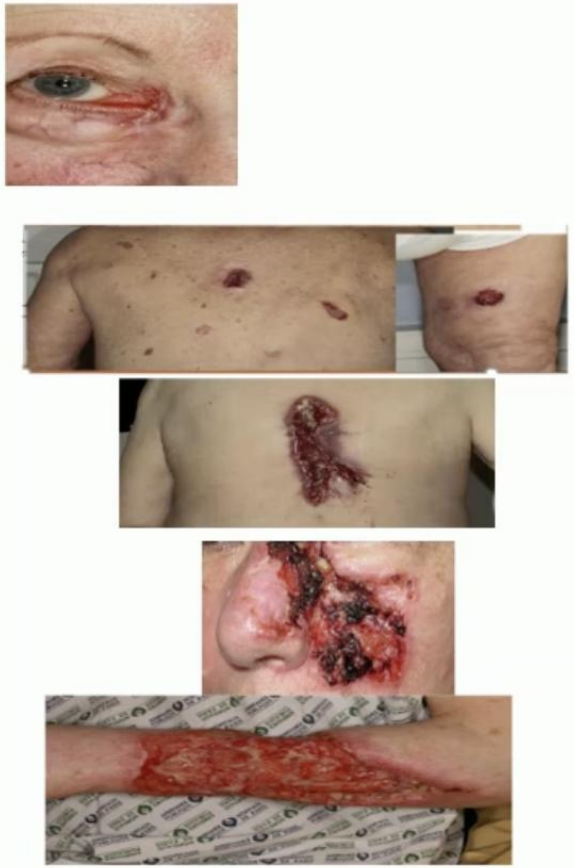
# CBC – tratamiento sistémico

- < 1%

(EADO classification: 5 Groups)

Difficult to treat (DTT)BCC

1. Common BCC DTT for X reasons
2. BCC because multiple lesions
3. La BCC outside a critical zone
4. LA BCC in a critical zone
5. Extremely advanced BCC



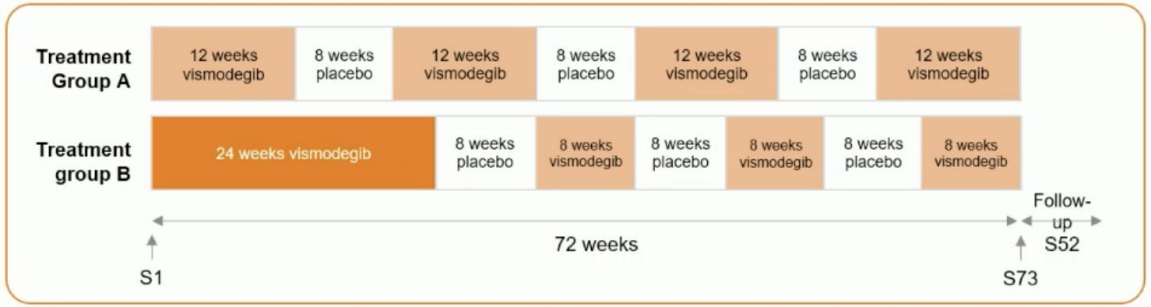
Slides by Dr. Lebbe

# CBC – tratamiento sistémico

Slides by Dr. Lebbe

- Inhibidores de hedgehog (vismodegib & sonidegib)
  - Tasas de respuesta aprox 50%
  - Problemas:
    - Tolerancia (EA: calambres musculares, disgeusia, pérdida de peso)
    - Resistencia (6%)
    - Recurrencias
    - Neoadyuvancia?

## Intermittent vismodegib regimens in patients with multiple BCC (MIKIE). Randomized, schedule-controlled, double-blind




| | MIKIE[1] (n = 229) | STEVIE[2] (n = 1 215) | ERIVANCE[3] (n = 104) |
|---|---|---|---|
| AEs leading to discontinuation treatment | 23 %<br>Group A: 20%, Group B: 34 | 31 % | 57 %* |
| AE ≥ grade 3 | 31 % | 44 % | 56 % |
| Median treatment duration (weeks) | 71 | 38 | 56 |

Interruption due to patient's decision (26%), doctor's decision (10%) or adverse effects (21%).

Conclusion: intermittent dosing regimens could be a useful strategy for patients with multiple BCCs requiring long-term treatment.

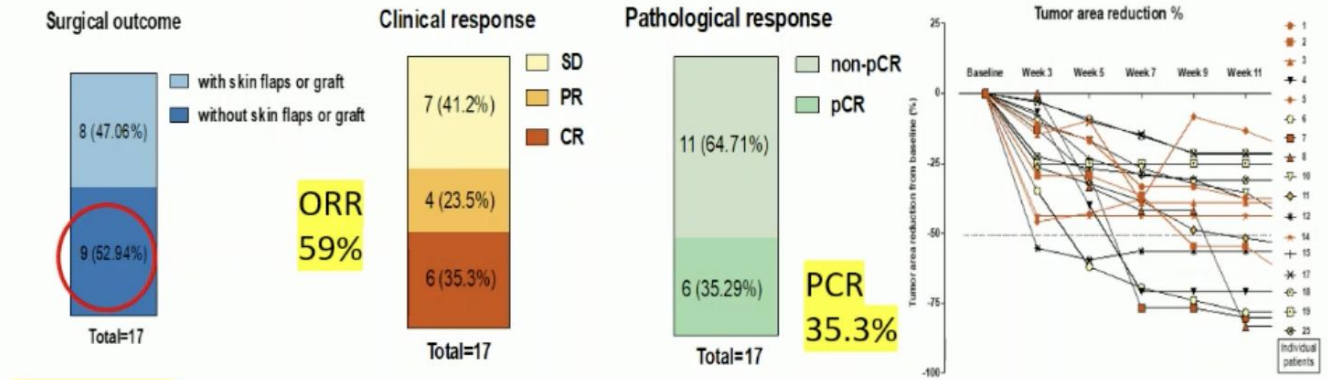
Adapted from Dréno B et al, Lancet Oncol 2017;18:404-12

# CBC – tratamiento sistémico

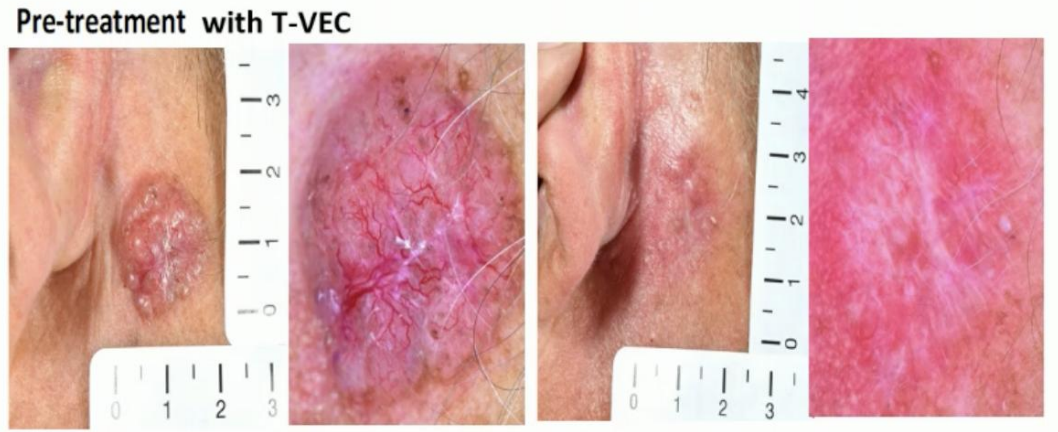
Slides by Dr. Lebbe

- 2a línea y futuro
  - Inmunoterapia (cemiplimab en EC)
    - Respuestas: 30%
  - T-VEC (EC)

## Neo-BCC Study: Tumor response




Avoid flap or graft: 52.9%




BCC, basal cell carcinoma; SD, stable disease; PR, partial response; CR, complete response; pCR, pathological complete response; T-VEC, talimogene laherparepvec

Christoph Hoeller
Department of Dermatology

Reissler Nature Cancer | Volume 6 | January 2025 | 51–66

2025 AEDV Highlights

34ª edición
17-20 sep
PARÍS

Brilla el futuro de *la dermatologia*,
donde nace *la luz*

# Carcinoma escamoso

ACADEMIA ESPAÑOLA DE DERMATOLOGÍA Y VENEREOLOGÍA

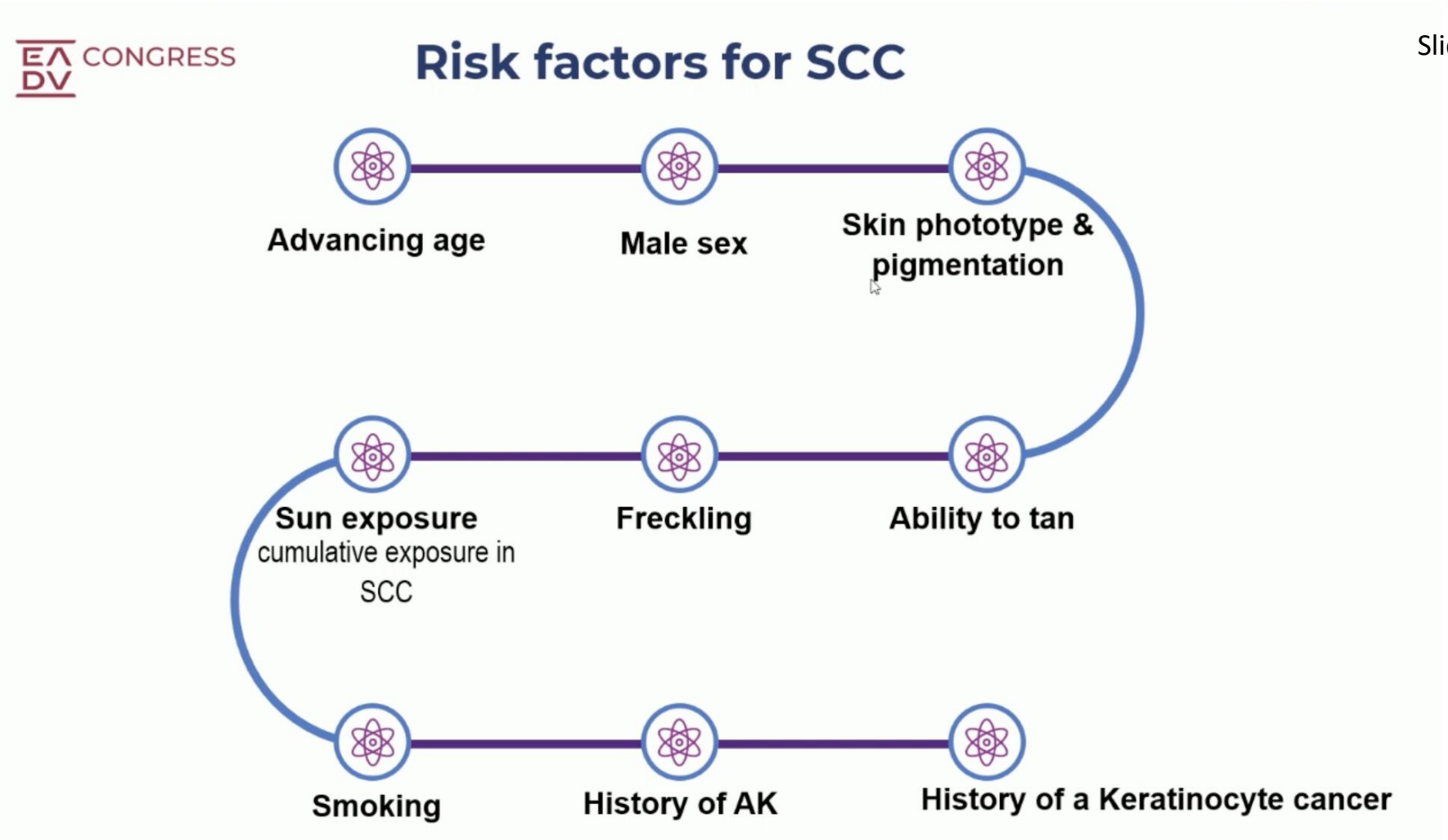
FUNDACIÓN AEDV PIEL SANA

ACADEMIA ESPAÑOLA DE DERMATOLOGÍA Y VENEREOLOGÍA

Patrocina: ucb

# CEC – Factores de riesgo

Slides by Dr. Khosrotehrani

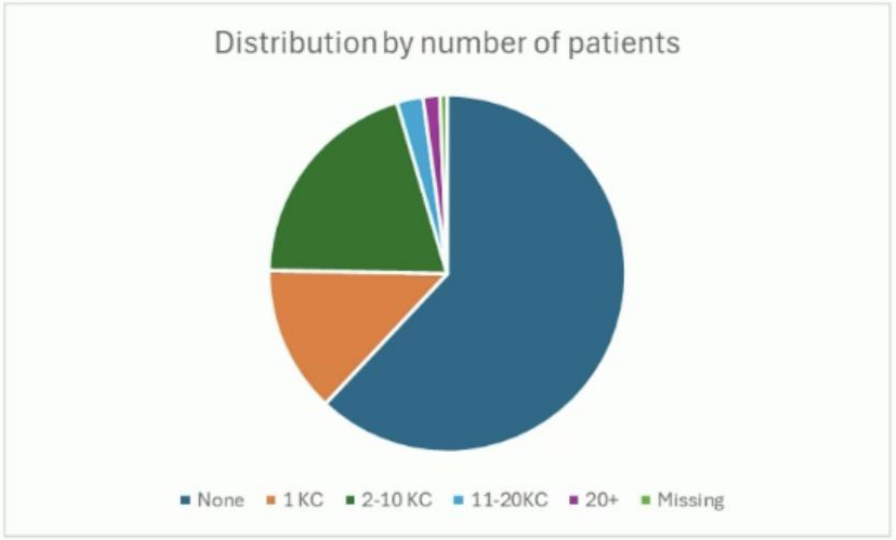


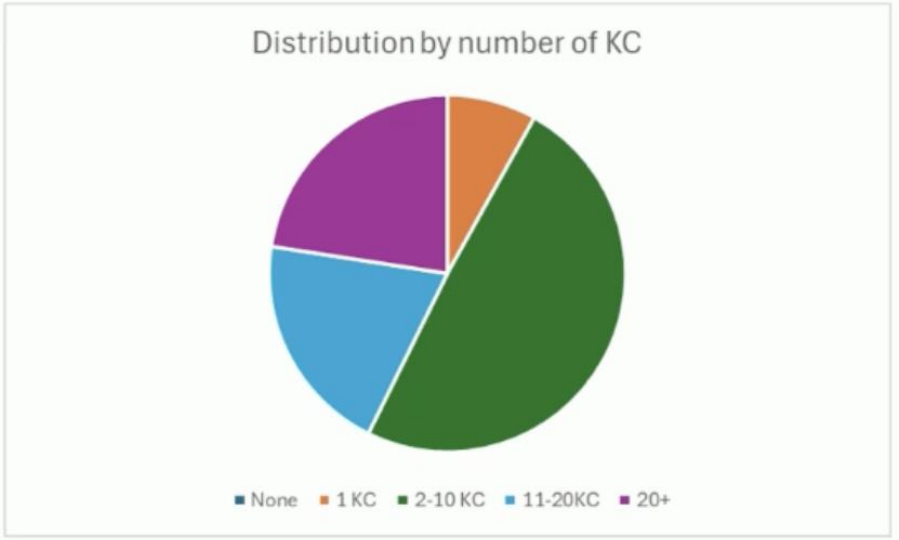
# CEC – Factores de riesgo

Slides by Dr. Khosrotehrani

EADV CONGRESS

## A small fraction carries most of the KC burden




3.8% of patients = 43% of all KCs

# CEC - Quimioprevención

- Protección solar
- Tópica
  - 5-FU +/- calcipotriol
- Sistémica

**Nicotinamide 500mg BD**
23% reduction in KC at 12 months
(Chen et al, NEJM 2015)
No effect in organ transplant recipients
(Allen et al, NEJM 2023)

**Acitretin 25mg, 5D per week**
Time to KC HR=0.47, (Kadakia et al Cancer 2012)

**Capecitabine**
72% reduction in KC in SOTR, (Endrizzi et al Dermatol Surg 2013)

**Poor tolerance of most effective agents restricts their use!**

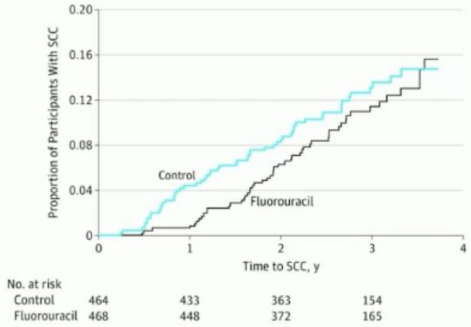
## Chemoprevention: Fluorouracil

Slides by Dr. Khosrotehrani

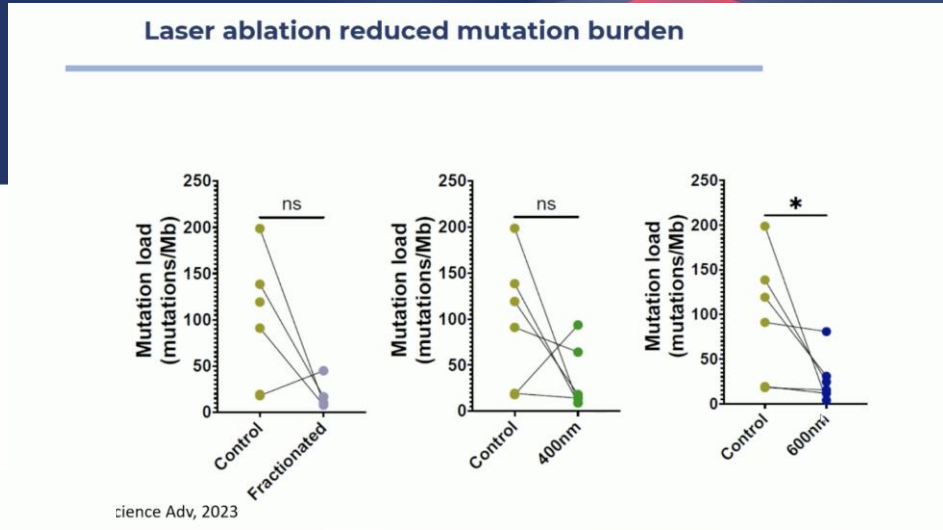
- Weinstock et al, JAMADerm 2018

Risk of Keratinocyte Carcinoma in Year 1 and Time to Outcome During Overall Study Period[a]

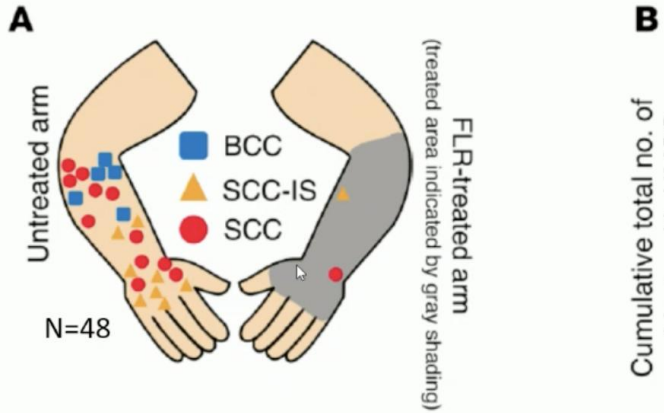
| Type of Lesion | Fluorouracil Group: Participants With ≥1 Lesion, No. (%) | Control Group: Participants With ≥1 Lesion, No. (%) | Hazard Ratio (95% CI) | Risk Ratio (95% CI) | *P* Value of Risk Ratio |
|---|---|---|---|---|---|
| | | Year 1 | | | |
| KC | 48 of 468 (10) | 63 of 464 (14) | 0.74 (0.51-1.08) | 0.76 (0.53-1.08) | .12 |
| BCC | 45 of 468 (10) | 50 of 464 (11) | 0.89 (0.59-1.33) | 0.89 (0.61-1.31) | .56 |
| SCC | 5 of 468 (1) | 20 of 464 (4) | 0.24 (0.09-0.65) | 0.25 (0.09-0.65) | .002 |

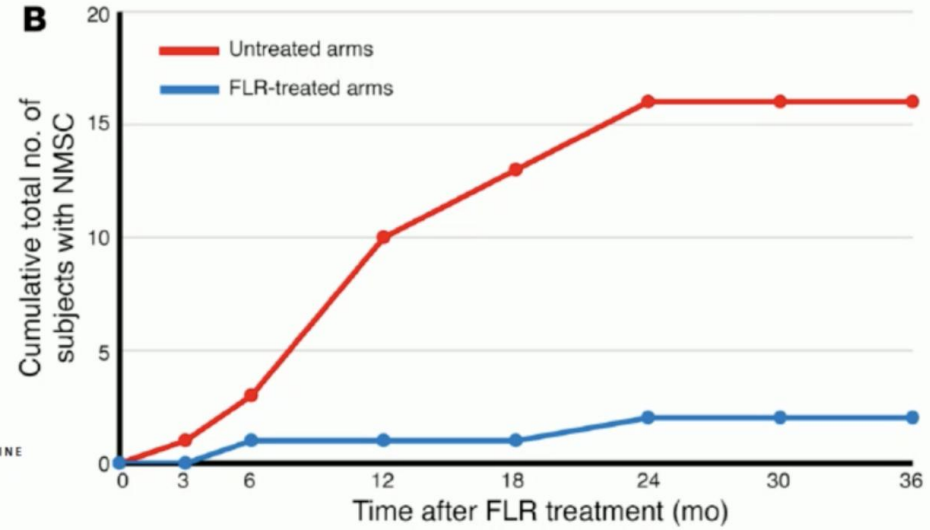


# CEC - Prevención




## Prevention of both SCCs and BCCs at 3 y




The Journal of Clinical Investigation

CLINICAL MEDICINE

**Randomized controlled trial of fractionated laser resurfacing on aged skin as prophylaxis against actinic neoplasia**

Dan F. Spandau,[1,2,3] Roy Chen,[4] Jeffrey J. Wargo,[5] Craig A. Rohan,[4,5] David Southern,[2] Angela Zhang,[2] Mathew Loesch,[2] Jonathan Weyerbacher,[2] Sunil S. Tholpady,[3,6] Davina A. Lewis,[2] Matthew Kuhar,[2,7] Kenneth Y. Tsai,[8] Amber J. Castellanos,[4] Michael G. Kemp,[4] Michael Markey,[5] Elizabeth Cates,[4] Amy R. Williams,[4] Christina Knisely,[4] Sabina Bashir,[4] Ryan Gabbard,[4] Robert Hoopes,[4] and Jeffrey B. Travers[4,9,10]

41

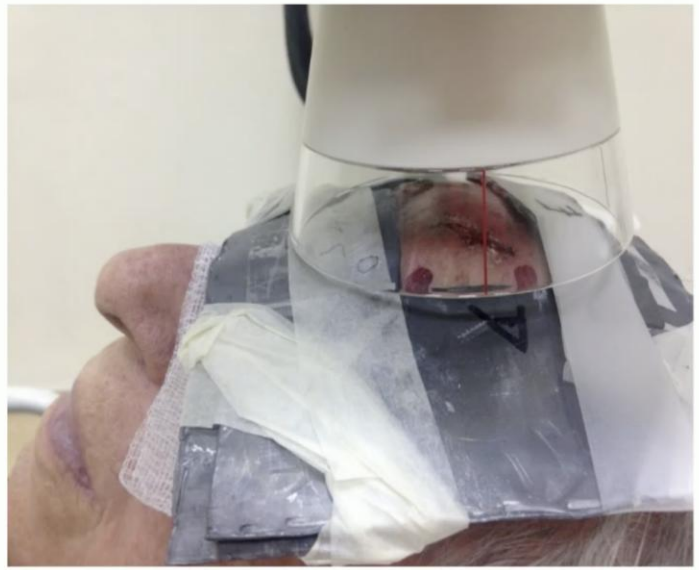
Slides by Dr. Khosrotehrani

# CEC – tratamientos no invasivos

Slides by Dr. Stratigos

- Tumores pequeños (in situ, áreas de bajo riesgo, campo cancerización)
- Pacientes (comorbilidad, localización área estética, preferencias)

## Radiotherapy in cSCC



European Guidelines. Part 2. 2023;

**6. Radiotherapy**

*6.1. Primary definitive radiotherapy*

Definitive primary radiotherapy represents a valid alternative and curative treatment strategy to surgery for small cSCCs. RT should be considered as the primary treatment option in patients who are not candidates for surgery (e.g. locally infiltrating cSCC not amenable to surgery, presence of comorbidities, or when patients decline surgery) or in cases when curative surgery is not possible or could be disfiguring or burdened by the poor functional outcome, especially cSCCs located on the face (i.e. eyelid, nose, lip) or large lesions on the ear, forehead, or scalp (Fig. 1).

5 year cure rate : 92% for BCC
80% for SCC

# CEC - tratamientos no invasivos

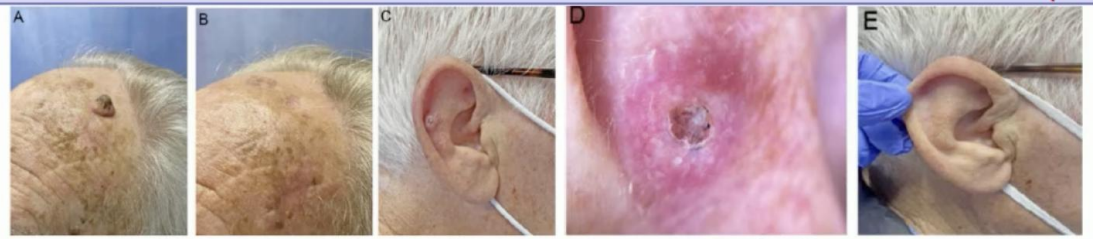
Slides by Dr. Stratigos

- Tratamientos intralesionales

## Methotrexate for KA

Kirby et al. JAAD 2025

| References | Tumor type | No. of tumors/ patients | Tumor diameter/ mean, cm | No. of treatments/ mean | Treatment frequency/ mean | Cure rate | Length of follow-up/ mean, mo |
|---|---|---|---|---|---|---|---|
| Annest et al, 2007 | KA | 18/18 | 1.0–3.5/2.1 | 1–3/2 | 12–38/22 | 15/18 (83%) | 1–91/23 |
| Cuesta-Romero and de Grado-Pena, 1998 | KA | 6/6 | 1.0–2.8/1.8 | 1–4/2.4 | NR | 6/6 (100%) | 10–20/13 |
| Cohen et al, 2005 | KA | 1/1 | NR | 3 | 14 | 1/1 (100%) | NR |
| Melton et al, 1991 | KA | 9/9 | 1.0–3.0/1.8 | 1–2/1.7 | 14 | 9/9 (100%) | 1–35/15 |
| de Visscher et al, 2002 | KA | 1/1 | 3.5 | 2 | 14 | 1/1 (100%) | 48 |
| Spieth et al, 2000 | KA | 1/1 | 2 | 5 | 7 | 1/1 (100%) | 1 |
| | | Total: 36/36 | Average: 1.98 | Average: 2.2 | | Total: 33/36 **(91.7%)** | Average: 19.5 |




**2 patients achieved complete resolution of KAs after IL methotrexate**

Torner N, et al.
*Actas Dermosifiliogr.* 2023

# CEC - tratamientos no invasivos

Slides by Dr. Stratigos

- Tratamientos intralesionales

## Intralesional T-VEC in Patients With cSCC

**11** participants
- Low-risk CSCC
- Unresectable lesions or unwilling to undergo SoC
- Immunocompetent

→ **T-VEC** *Up to 4 injections* → 1-year follow-up

### Results

| Outcome | Result (N=11) |
|---|---|
| **ORR**, n (%) | 11 (**100**) |
| **CR**, n (%) | 10 (**90.9**) |
| DoR, days | 206 ± 26 |

| Adverse event | (N=11) |
|---|---|
| Fatigue, n (%) | 5 (45.5) |
| Flu-like symptoms, n (%) | 4 (36.4) |
| Headache, n (%) | 2 (18.2) |

Curiel CN, et al. A single arm phase 2 study of talimogene laherparepvec in patients with low-risk invasive cutaneous squamous cell cancer. interim analysis. 2022;40(16_suppl):e21583

# CEC - tratamientos no invasivos

Slides by Dr. Stratigos

## Off-label T-VEC for in-transit metastases of cSCC in a liver transplant patient

- cSCC on arm, history of 4 Mohs surgeries, RT
- Two years after initial diagnosis: in-transit metastasis
- T-VEC every 2 w over 15 months
- At 1 year, most lesions cleared
- One resistant: surgery

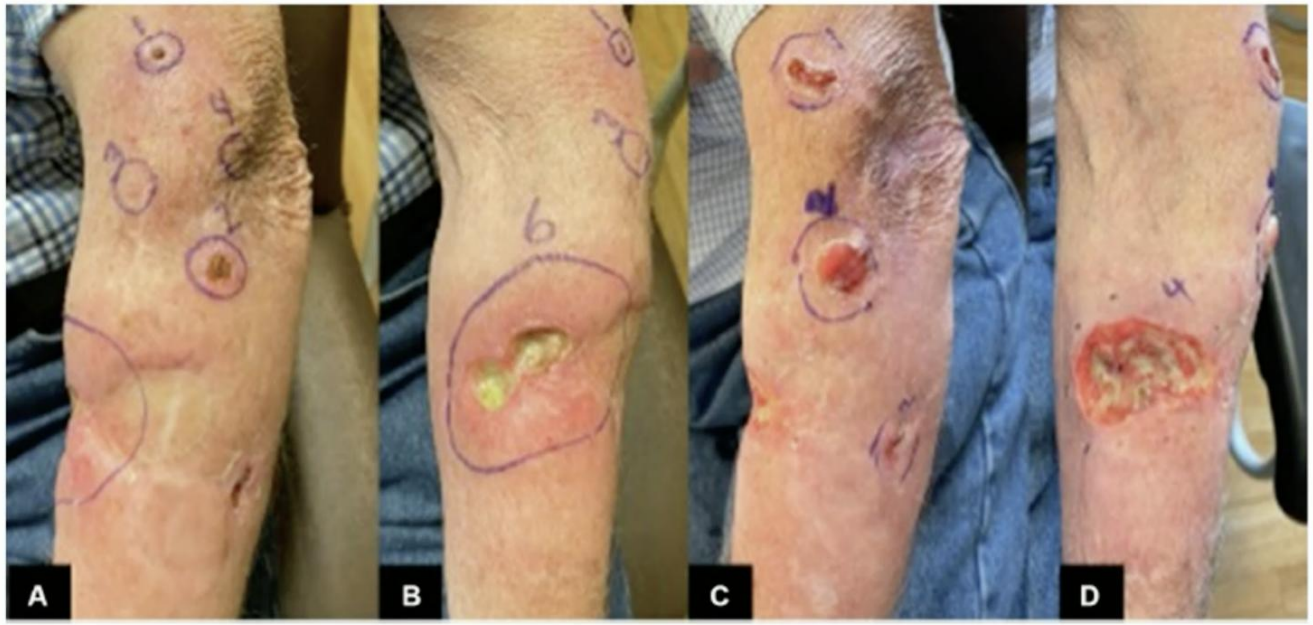



**Fig 1.** *Left forearm* notable for multiple in-transit lesions of various sizes. Images (**A** and **B**), were taken on T-VEC treatment 2 (day 21) and images (**C** and **D**), on treatment 16 (day 217).

Lebhar et al. JAADCase Rep 2023

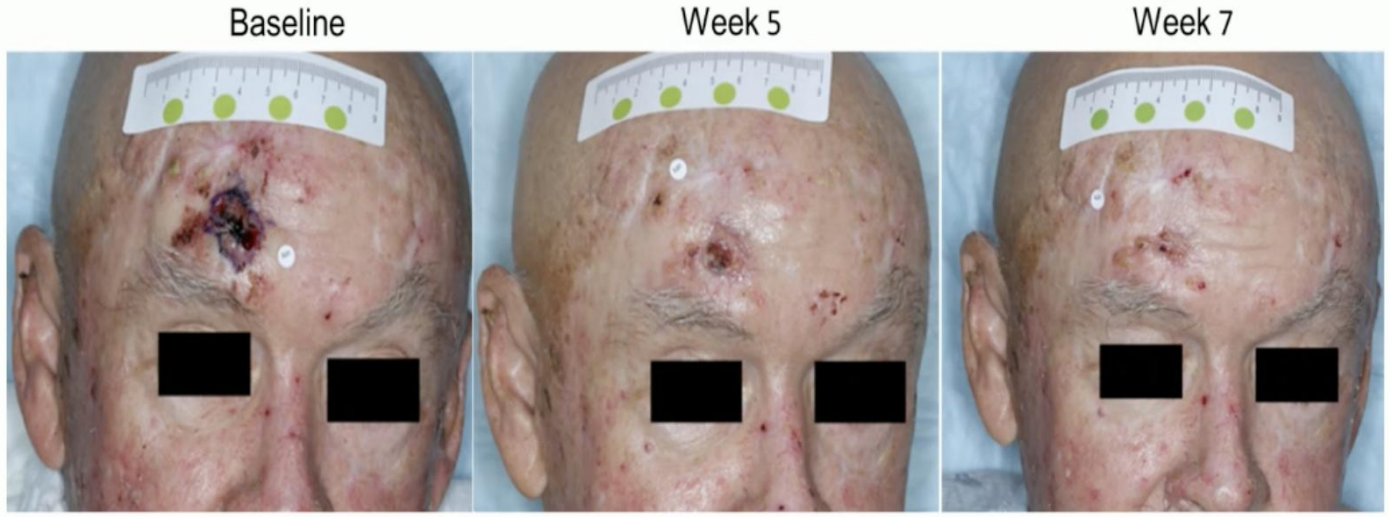
# CEC - tratamientos no invasivos

Slides by Dr. Stratigos

- EC

## Intralesional therapy with Cemiplimab in cSCC

| | Dose Level 1: 5 mg QW (N=8) | Dose Level 2: 15 mg QW (N=3) | Dose Level 3: 44 mg QW (N=6) | Total (N=17) |
|---|---|---|---|---|
| Pathologic Response Rate (pCR), N (%) | 6 (75.0%) | 2 (66.7%) | 5 (83.3%) | 13 (76.5%) |

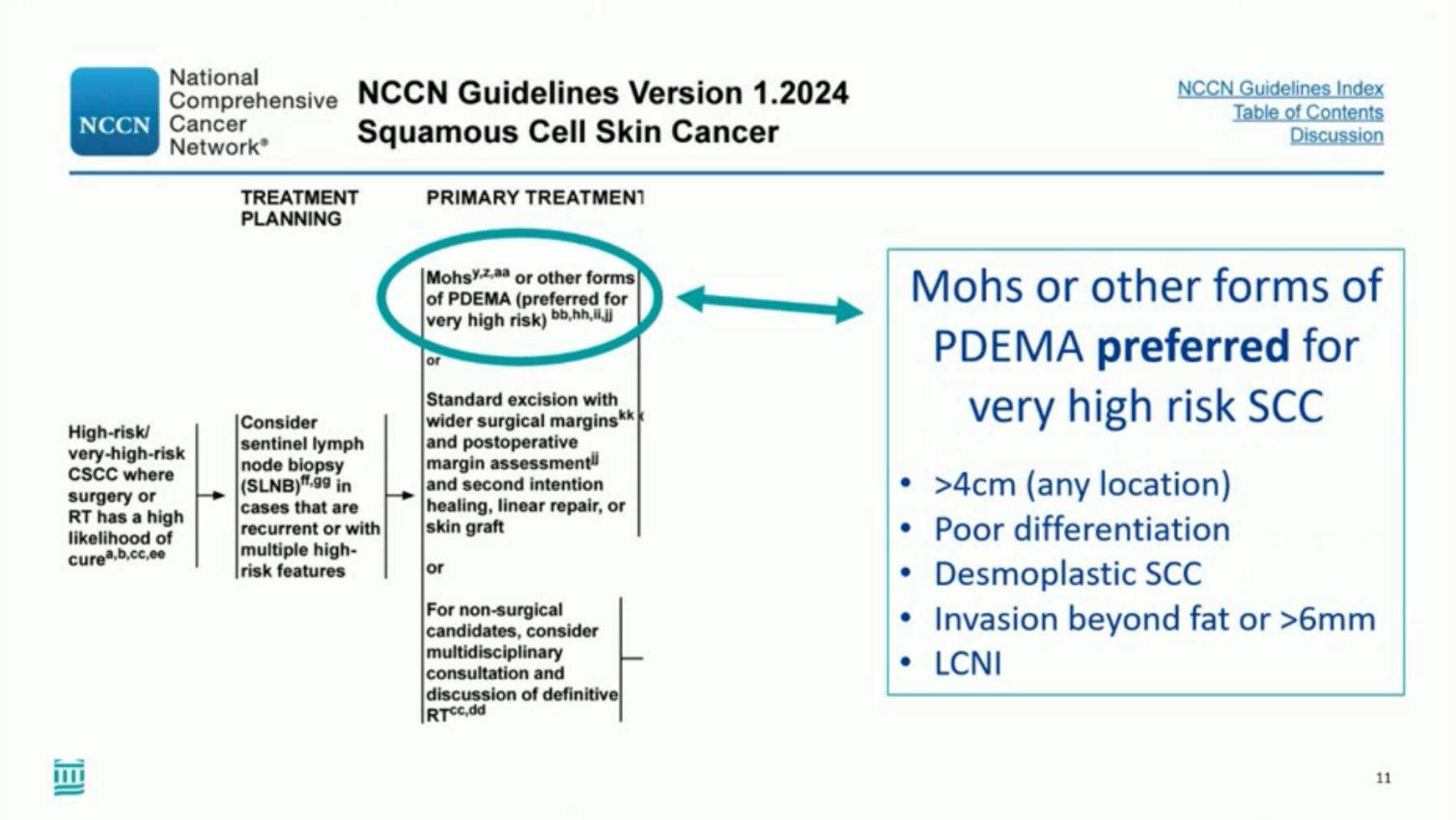



Effect of cemiplimab 5 mg QW (DL1) in a patient with recurrent CSCC

Midgen MR, Presented at the AMCMS 2022 Scientific Meeting

# CEC – Tratamiento tumores avanzados

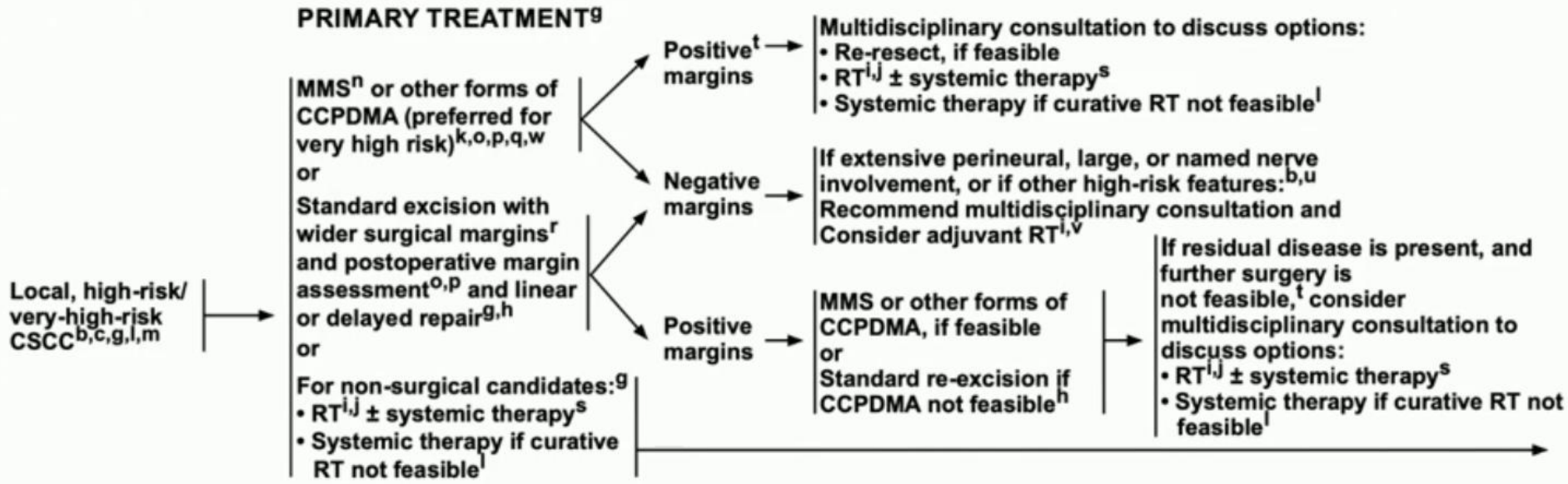
Slides by Dr. Ruiz



# CEC – Tratamiento tumores avanzados

Slides by Dr. Ruiz

## NCCN Guidelines




**Surgery +/- adjuvant radiation = current standard of care**

# CEC – Tratamiento tumores avanzados

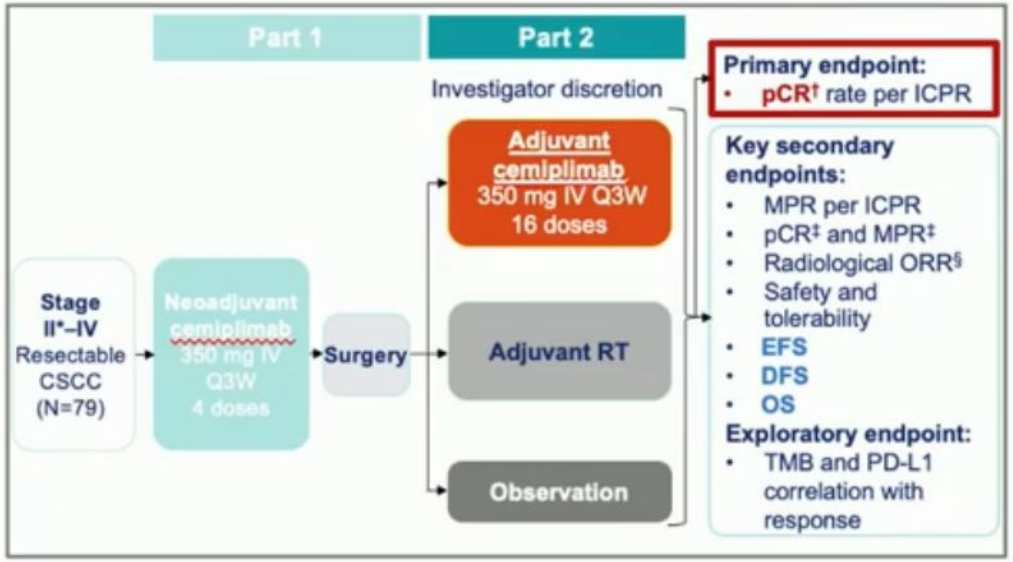
Slides by Dr. Ruiz

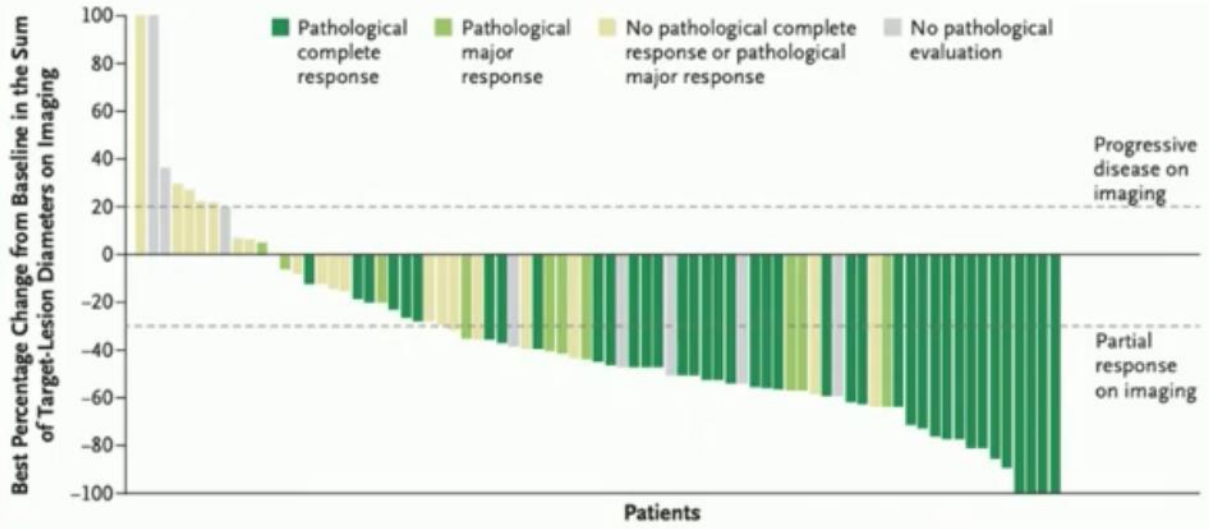
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

## Neoadjuvant Cemiplimab for Stage II to IV Cutaneous Squamous-Cell Carcinoma

N.D. Gross, D.M. Miller, N.I. Khushalani, V. Divi, E.S. Ruiz, E.J. Lipson, F. Meier, Y.B. Su, P.L. Swiecicki, J. Atlas, J.L. Geiger, A. Hauschild, J.H. Choe, B.G.M. Hughes, D. Schadendorf, V.A. Patel, J. Homsi, J.M. Taube, A.M. Lim, R. Ferrarotto, H.L. Kaufman, F. Seebach, I. Lowy, S.-Y. Yoo, M. Mathias, K. Fenech, H. Han, M.G. Fury, and D. Rischin




**51% pCR! 13% MPR!**

# CEC – Tratamiento tumores avanzados

Slides by Dr. Ruiz

ORIGINAL ARTICLE

## Adjuvant Cemiplimab or Placebo in High-Risk Cutaneous Squamous-Cell Carcinoma

D. Rischin,[1,2] S. Porceddu,[3] F. Day,[4] D.P. Brungs,[5,6] H. Christie,[7] J.E. Jackson,[8] B.N. Stein,[9] Y.B. Su,[10] R. Ladwa,[11] G. Adams,[12] S.E. Bowyer,[13] Z. Otty,[14] N. Yamazaki,[15] P. Bossi,[16,17] A. Challapalli,[18] A. Hauschild,[19] A.M. Lim,[1,2] V.A. Patel,[20] J.L. Walker,[21] M. De Liz Vassen Schurmann,[22] P. Queirolo,[23] J. Cañueto,[24] F.A. Ferreira da Silva,[25] A. Stratigos,[26] A. Guminski,[27] C. Lin,[28,29] F. Damian,[30] L. Flatz,[31] A.E. Taylor,[32] D.R. Carr,[33] S. Harris,[34] D. Kirtbaya,[35] G. Quereux,[36] P. Rutkowski,[37] N. Basset-Seguin,[38] N.I. Khushalani,[39] C. Robert,[40] H. Ju,[41] C. Joseph,[41] S. Bansal,[41] C.-I Chen,[41] F. Seebach,[41] S.-Y. Yoo,[41] I. Lowy,[41] P. Goncalves,[41] and M.G. Fury,[41] for the C-POST Trial Investigators*

### Nodal and Non-Nodal High-Risk Criteria*

| Nodal disease | In-transit metastases | Perineural invasion | T4 lesions | Recurrent CSCC |
|---|---|---|---|---|
| ECE with ≥1 node ≥20 mm OR ≥3 nodes regardless of ECE | Skin or subcutaneous metastases >20 mm from the primary lesion but not beyond the regional nodal basin | Clinical and/or radiologic involvement of named nerves | Invasion of cortical bone or skull base | CSCC that arises within the area of previously resected tumor, plus ≥1 additional feature** |

**Additional features for recurrent lesion:

- ≥N2b
- ≥T3
- Poorly differentiated histology and recurrent lesion ≥20 mm diameter

# CEC – Tratamiento tumores avanzados

Slides by Dr. Ruiz

## Efficacy and safety of cosibelimab, an anti-PD-L1 antibody, in metastatic cutaneous squamous cell carcinoma

Philip Clingan,[1] Rahul Ladwa,[2] Daniel Brungs,[1,3] Dean Laurence Harris,[4] Margaret McGrath,[5] Susan Arnold,[6] Jermaine Coward,[7] Samuel Fourie,[8] Andriy Kurochkin,[9] Daniel R Malan,[10] Andrew Mant,[11] Vinay Sharma,[12] Hong Shue,[13] Andrea Tazbirkova,[14] Miguel-Angel Berciano-Guerrero ,[15] Chaiyut Charoentum,[16] Stéphane Dalle,[17] Arunee Dechaphunkul,[18] Oleksandr Dudnichenko,[19] Piotr Koralewski,[20] Iwona Lugowska,[21] Henri Montaudié,[22] Eva Muñoz-Couselo,[23] Virote Sriuranpong,[24] James Oliviero ,[25] Jayesh Desai[26]

**Table 2** Tumor response by ICR according to RECIST V.1.1

| Parameter, n (%)* | mCSCC (N=78) |
|---|---|
| Best overall response | |
| Complete response | 6 (7.7) |
| Partial response | 31 (39.7) |
| Stable disease | 12 (15.4) |
| Progressive disease | 21 (26.9) |
| Not evaluable | 8 (10.3) |
| ORR in ITT population, % (95% CI) | 47.4 (36.0 to 59.1) |
| ORR in modified ITT population, % (95% CI) | 48.7 (37.0 to 60.4)† |
| Response ongoing | 27 (73.0) |
| Median DOR, months (min, max) | NR (1.4+ to 34.1+) |
| Kaplan-Meier-estimated 6-month DOR probability, % (95% CI) | 88.9 (73.1 to 95.7) |
| Kaplan-Meier-estimated 12-month DOR probability, % (95% CI) | 73.0 (54.2 to 85.0) |
| Kaplan-Meier-estimated 24-month DOR probability, % (95% CI) | 73.0 (54.2 to 85.0) |
| Median duration of follow-up, months (95% CI) | 15.4 (12.0 to 21.0) |

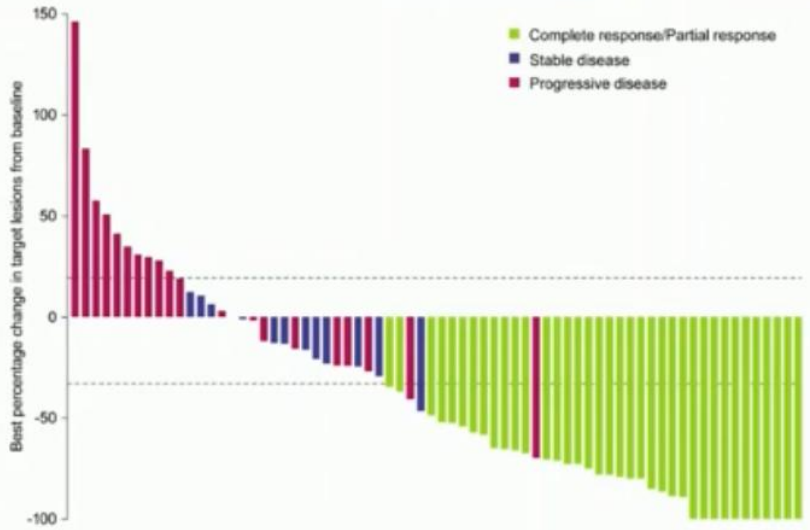



**Table 3** Summary of TEAEs

| TEAE, n (%) | Any grade (N=78) | Grade ≥3 (N=78) |
|---|---|---|
| Any | 76 (97.4) | 41 (52.6) |
| Immune-related TEAE | 18 (23.1) | 2 (2.6) |
| TEAEs, regardless of attribution, that led to discontinuation | 9 (11.5) | 8 (10.3) |

Clingan P, *et al. J Immunother Cancer* 2023;**11**:e007637. doi:10.1136/jitc-2023-007637 

# CEC – Tratamiento tumores avanzados

Slides by Dr. Ruiz

## Cemiplimab for Kidney Transplant Recipients With Advanced Cutaneous Squamous Cell Carcinoma

Glenn J. Hanna, MD[1]; Harita Dharanesswaran, BS[2]; Anita Giobbie-Hurder, MS[3]; John J. Harran, RN[2]; Zixi Liao, RN[2]; Lori Pai, MD[4]; Vatche Tchekmedyian, MD[5]; Emily S. Ruiz, MD[2]; Abigail H. Waldman, MD[2]; Chrysalyne D. Schmults, MD[2]; Leonardo V. Riella, MD, PhD[6]; Patrick Lizotte, PhD[7]; Cloud P. Paweletz, PhD[7]; Anil K. Chandraker, MD, MBCHB[8]; Naoka Murakami, MD, PhD[9]; and Ann W. Silk, MD[2]

ASCO Journal of Clinical Oncology

## Nivolumab + Tacrolimus + Prednisone ± Ipilimumab for Kidney Transplant Recipients With Advanced Cutaneous Cancers

Kara M. Schenk, MD[1,2]; Julie Stein Deutsch, MD[3,4]; Sunandana Chandra, MD, MS[5]; Diwakar Davar, MD[6]; Zeynep Eroglu, MD[7]; Nikhil I. Khushalani, MD[7]; Jason J. Luke, MD, FACP[8]; Patrick A. Ott, MD, PhD[9]; Jeffrey A. Sosman, MD[5]; Vikram Aggarwal, MD[10]; Megan D. Schollenberger, CRNP[5]; William H. Sharfman, MD[2,4]; Kristin P. Bibee, MD, PhD[2]; Jeffrey F. Scott, MD, FACS[2,11]; Manisha J. Loss, MD[2]; Hao Wang, PhD[4,12]; Hanfei Qi, MS[12]; Elad Sharon, MD[13]; Howard Streicher, MD[13]; Helen X. Chen, MD[13]; Robert N. Woodward, PhD[2,4]; Serena M. Bagnasco, MD[2,5]; Janis M. Taube, MD, MSc[3,4]; Suzanne L. Topalian, MD[4,14]; Daniel C. Brennan, MD[17]; and Evan J. Lipson, MD[2,4]

### Clinical Trial Schemas

**Hanna trial**

Eligibility:
- Patients with advanced or metastatic CSCC
- Renal transplant
- 12 patients

Cemiplimab IV once every 21 days

+

Everolimus/sirolimus AND pulsed-dose steroids (40 mg-20 mg-10 mg once daily)

→ 12 RTRs
0 Graft Losses
Response: 64% clinical benefit
-3/11 CR
-2/11 PR
-2/11 SD

**Schenk trial**

Eligibility:
- Patients with advanced or metastatic cutaneous cancers
- Renal transplant
- Nine patients

Nivolumab

+

Tacrolimus (5 mg/mL once daily) AND prednisone (5 mg once daily)

Upon progression → Nivolumab + ipilimumab

→ 8 RTRs
33% Graft Losses
Response:
Nivo Mono: 0/8 responses
Ipi+Nivo: 33% response rate
-2/6 CR
-1/6 SD

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ACADEMIA ESPAÑOLA DE DERMATOLOGÍA Y VENEREOLOGÍA

Patrocina: ucb

# 2025 AEDV Highlights

34ª edición
17-20 sep
PARÍS

Brilla el futuro de *la dermatologia*,
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**La Academia Española de Dermatología y Venereología expresa su agradecimiento al patrocinador UCB, por su especial apoyo y contribución con la actividad formativa Highlights 2025.**

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