SCU Sociedad Canaria de Urología

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CARCINOMA DE CELULAS RENALES

@PJimenezMarrero

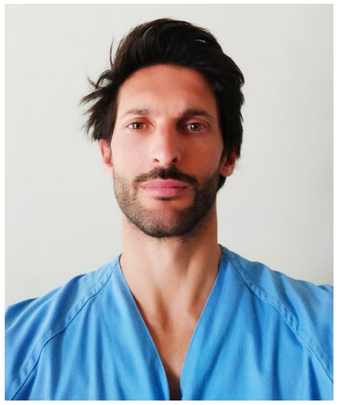
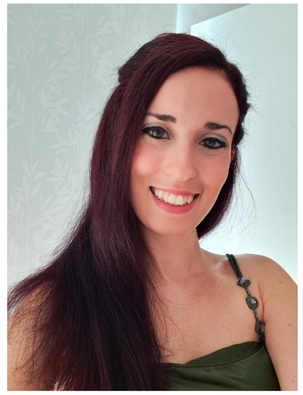
Pablo Jiménez Marrero

Sep 2023

Reunión Comité Uro-Oncología

CARCINOMA DE CELULAS RENALES

- Lucía Moreno (Urología)
- Saray Galván (Oncología Médica)
- Ivone Ribeiro (Oncología Radioterápica)
- Jose Luis Pareja (Radiodiagnóstico)
- Lidia González (Anatomía Patológica)
- Marta Piñero (Farmacia)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Pablo Jiménez
8 Noviembre 2022

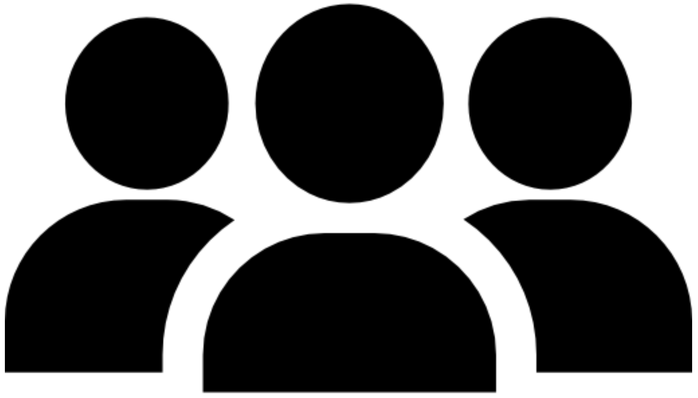
CARCINOMA DE CELULAS RENALES

- Epidemiología
- Etiología
- Histología
- Clínica
- Diagnóstico
- Tratamiento
- Conclusiones

"upon" "study"

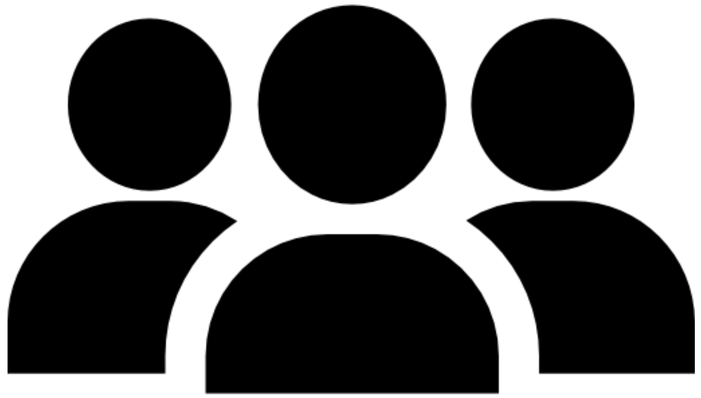
epidemiology

"people"



Carcinoma de Células Renales

Epidemiologia:



¿Que lugar ocupa el mundo CCR en España?

¿Y con respecto al resto del mundo??

Estadio y Pronóstico

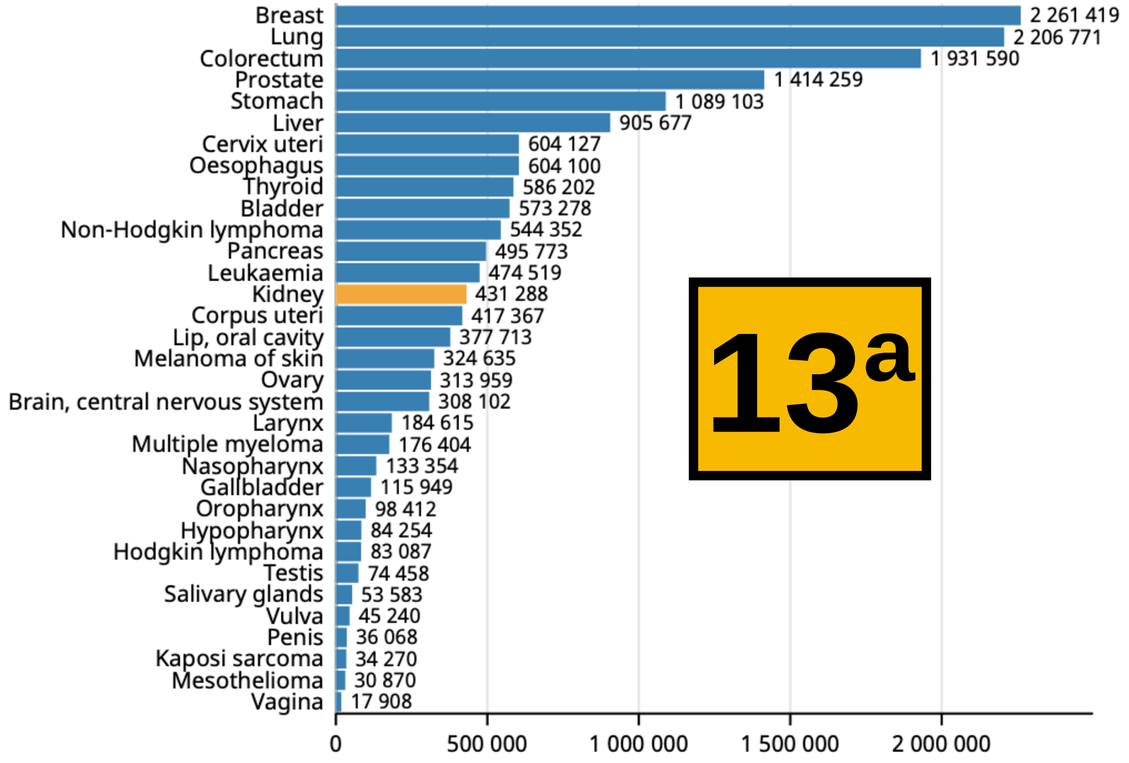
¿Cuanto se estima que viva un pacinete con un CCR?

Factores de Riesgo

Kidney

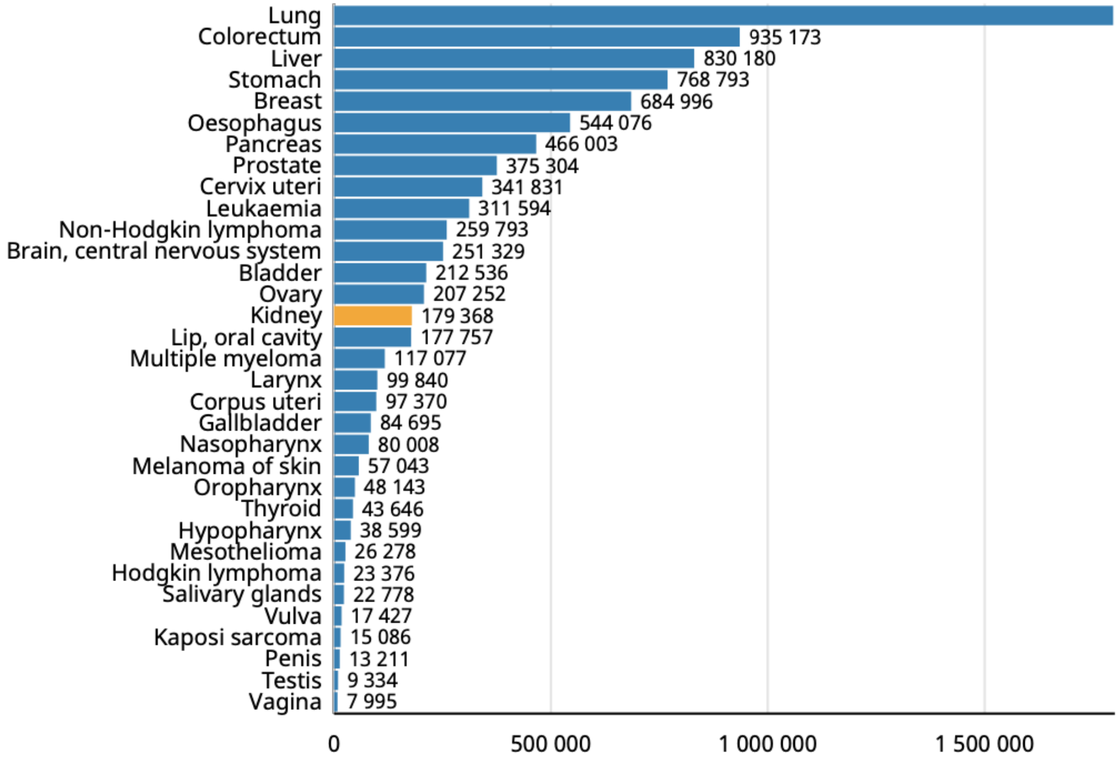
Source: Globocan 2020

Number of new cases in 2020, both sexes, all ages



13ª

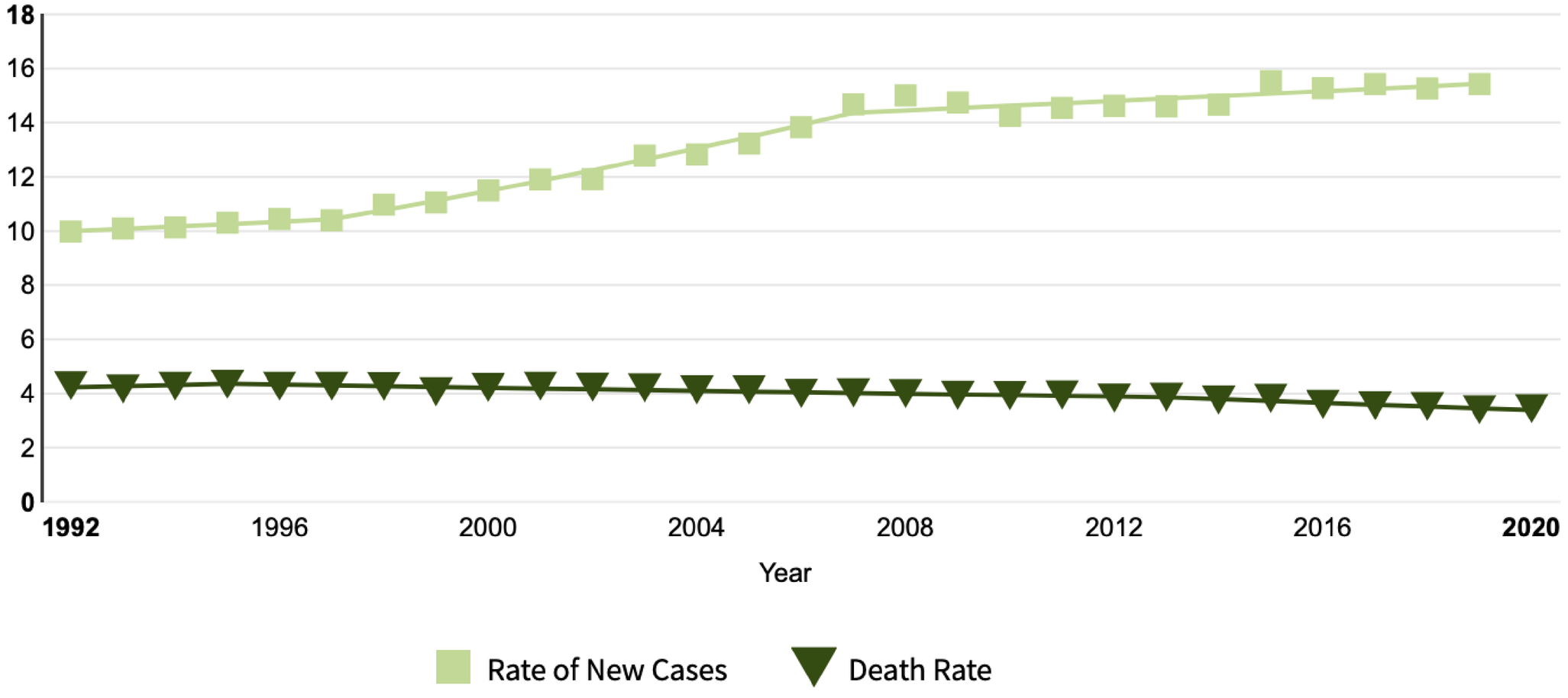
Number of deaths in 2020, both sexes, all ages

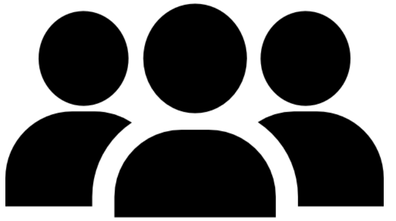


SEER Surveillance, Epidemiology, and End Results

Turning Cancer Data Into Discovery

US

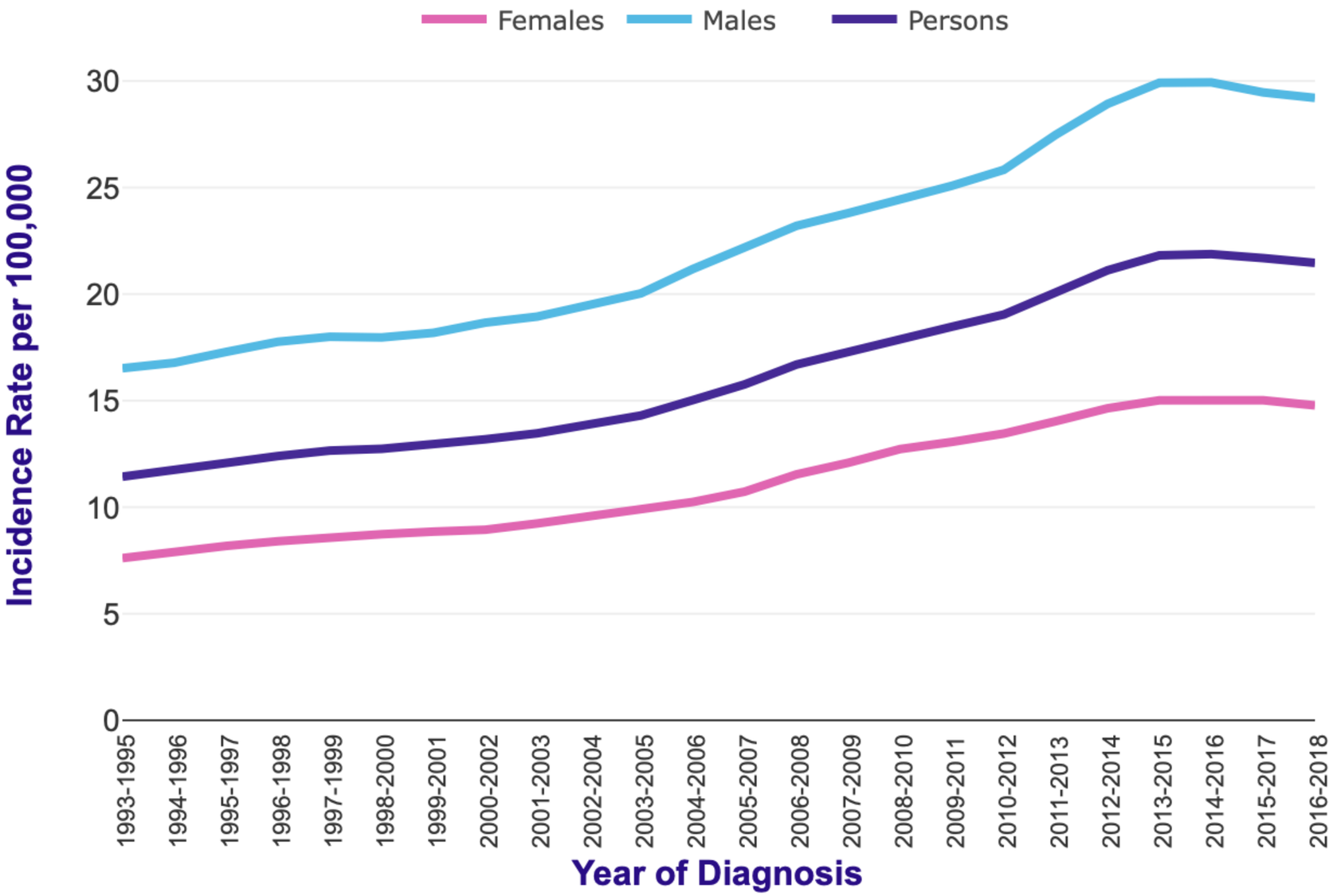




CANCER RESEARCH UK

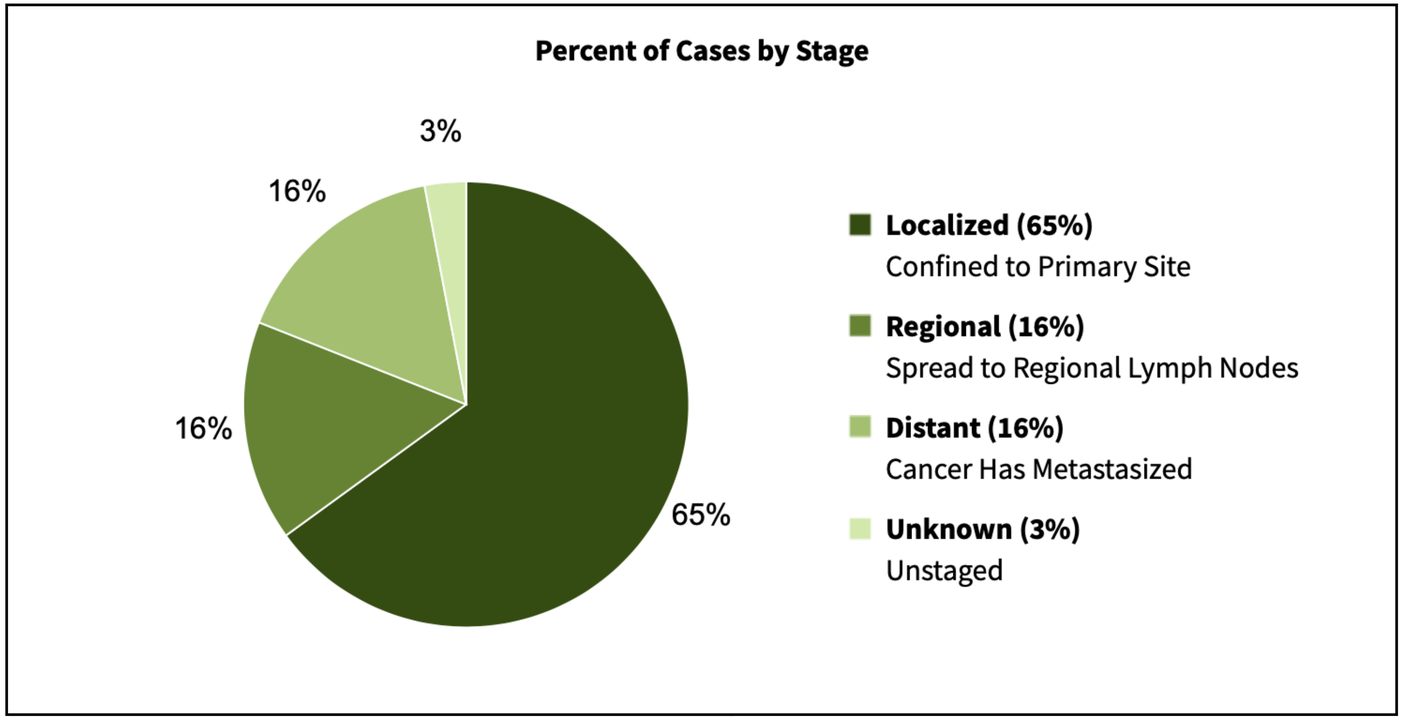
Together we will beat cancer

GB

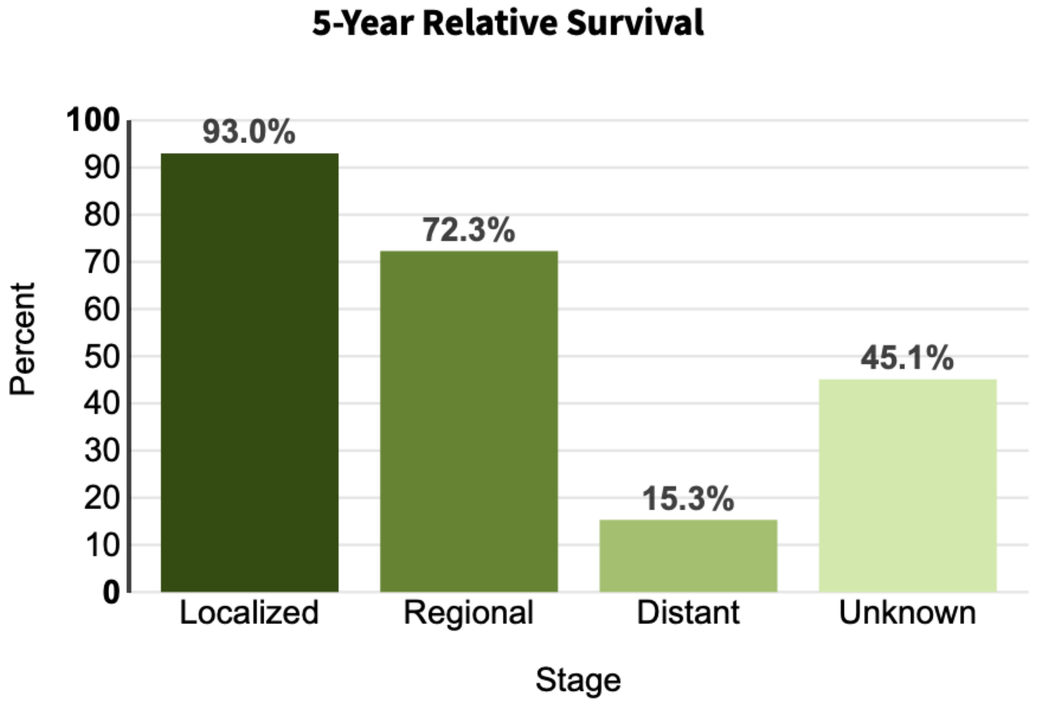


US


Surveillance, Epidemiology, and End Results
Turning Cancer Data Into Discovery
SEER


Percent of Cases by Stage
3%
16%
16%
65%
Localized (65%)
Confined to Primary Site
Regional (16%)
Spread to Regional Lymph Nodes
Distant (16%)
Cancer Has Metastasized
Unknown (3%)
Unstaged


5-Year
Relative Survival
76.5%

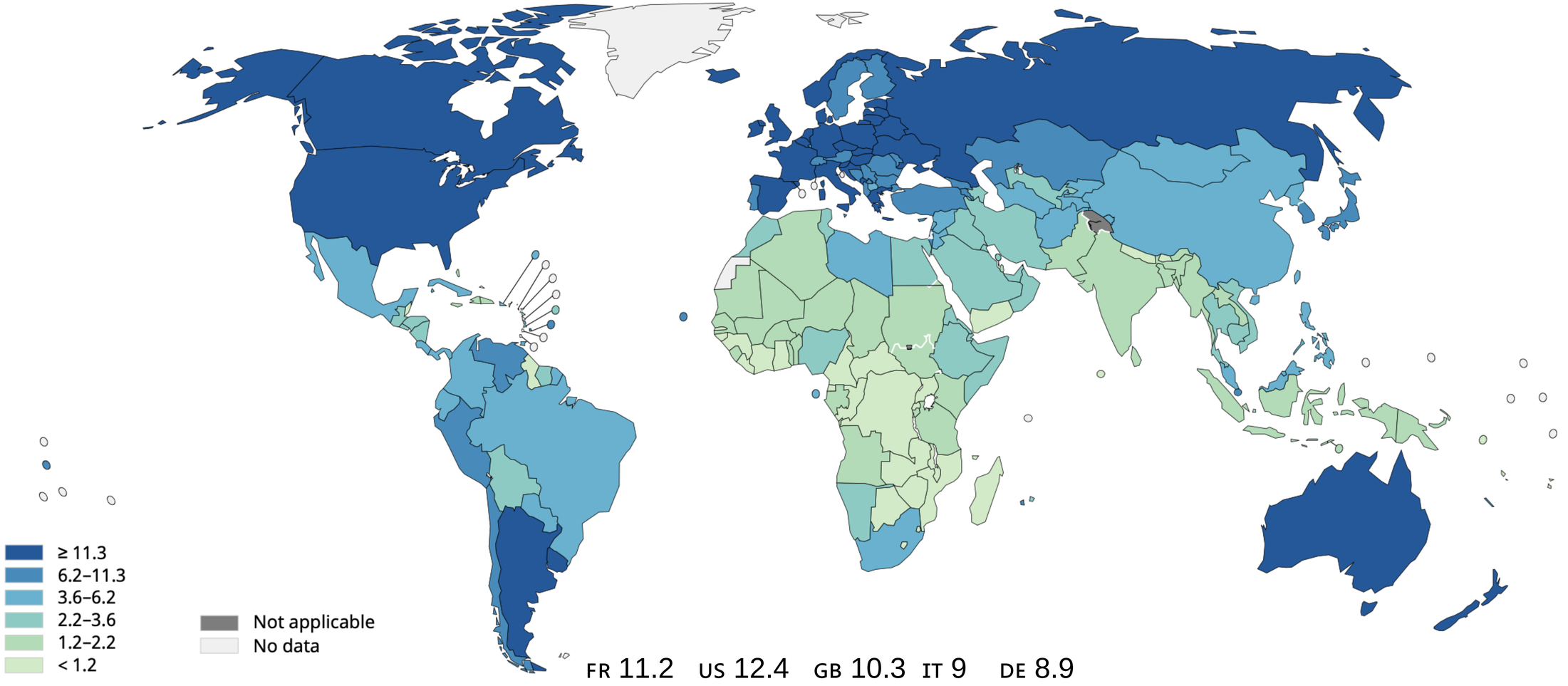

5-Year Relative Survival
Percent
100
90
80
70
60
50
40
30
20
10
0
93.0%
72.3%
15.3%
45.1%
Localized
Regional
Distant
Unknown
Stage

International Agency for Research on Cancer

World Health Organization

GLOBAL CANCER OBSERVATORY

Age standardized (World) incidence rates, kidney, males, all ages

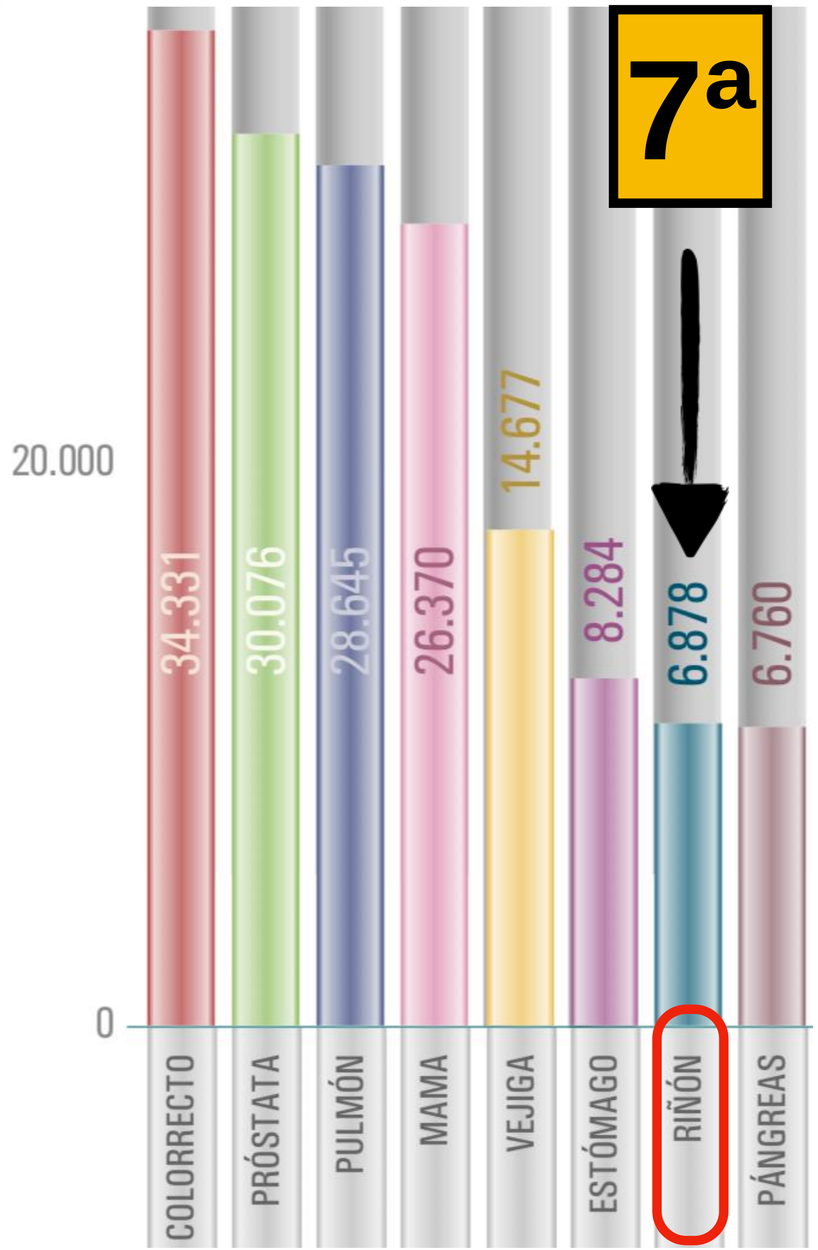


ES ESPAÑA: 9

https://gco.iarc.fr December, 2020

ES

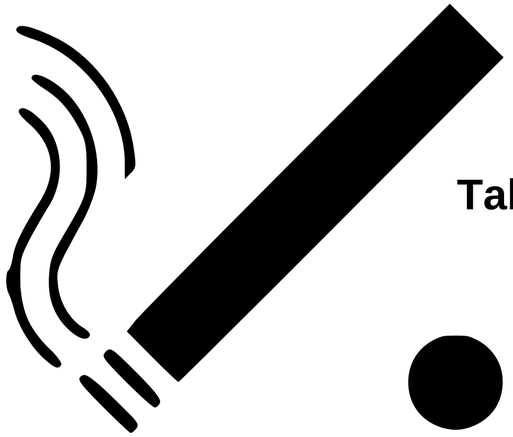
Las Cifras del Cáncer en España 2018



2 : 1

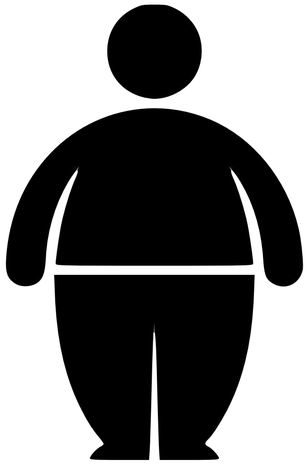
6ª

13ª

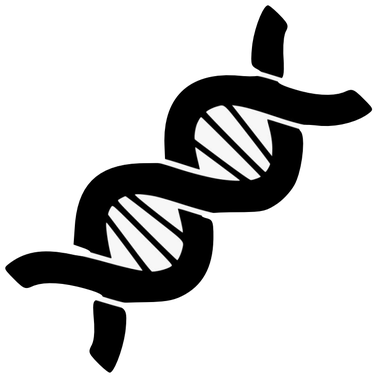


Tabaco

Edad



Obesidad



Familiar

Diabetes

HTA

Together we will beat cancer

CANCER RESEARCH UK

Preventable cases

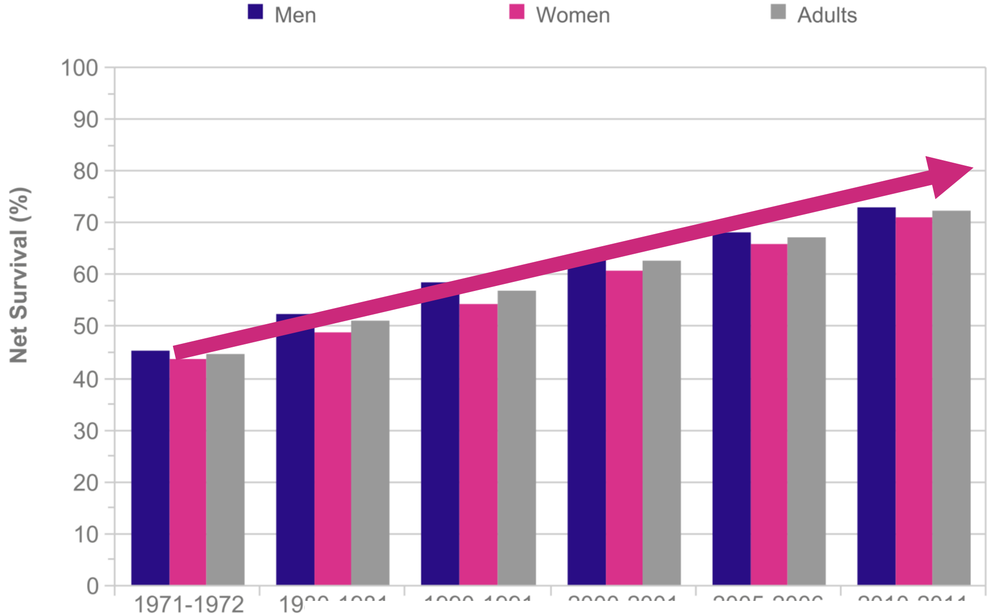
Kidney cancer cases are preventable, UK, 2015

Caused by obesity

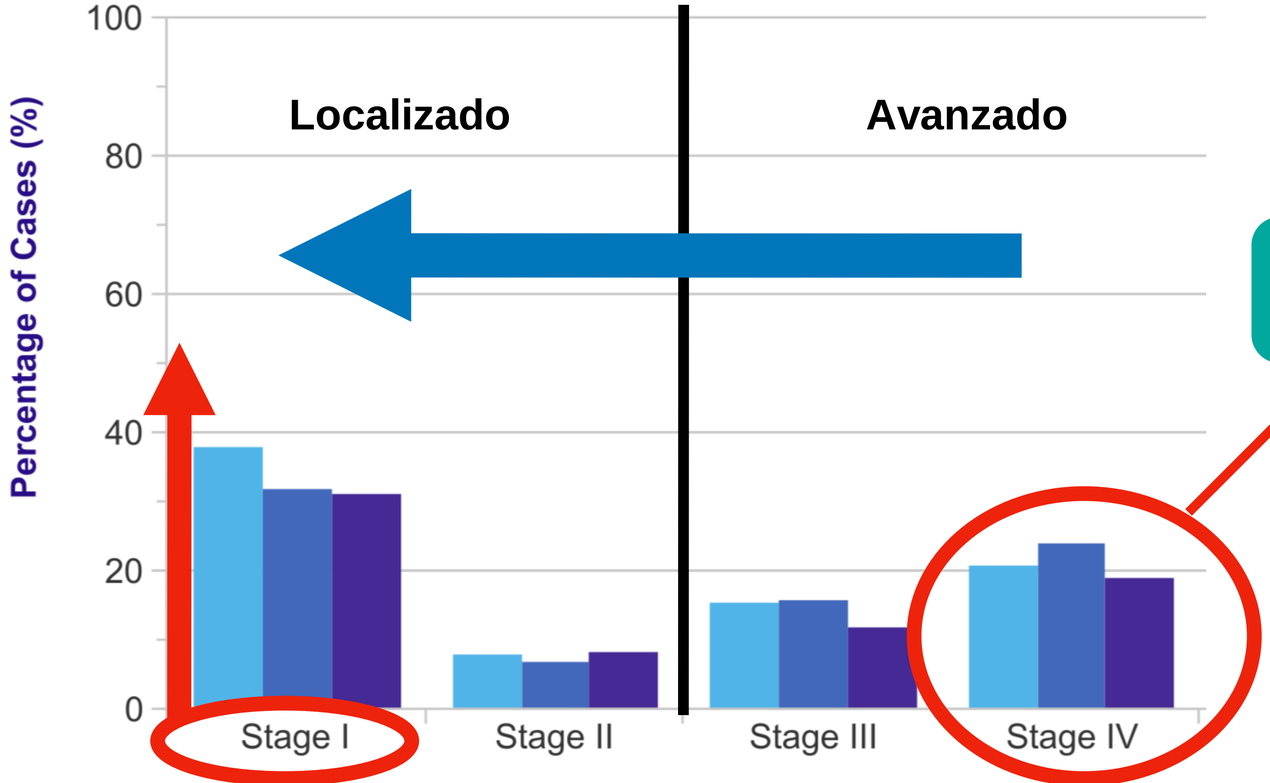
Kidney cancer cases caused by overweight and obesity, UK, 2015

Caused by smoking

Kidney cancer cases caused by smoking, UK, 2015



↑ **Diagnóstico**



Terapias Diana

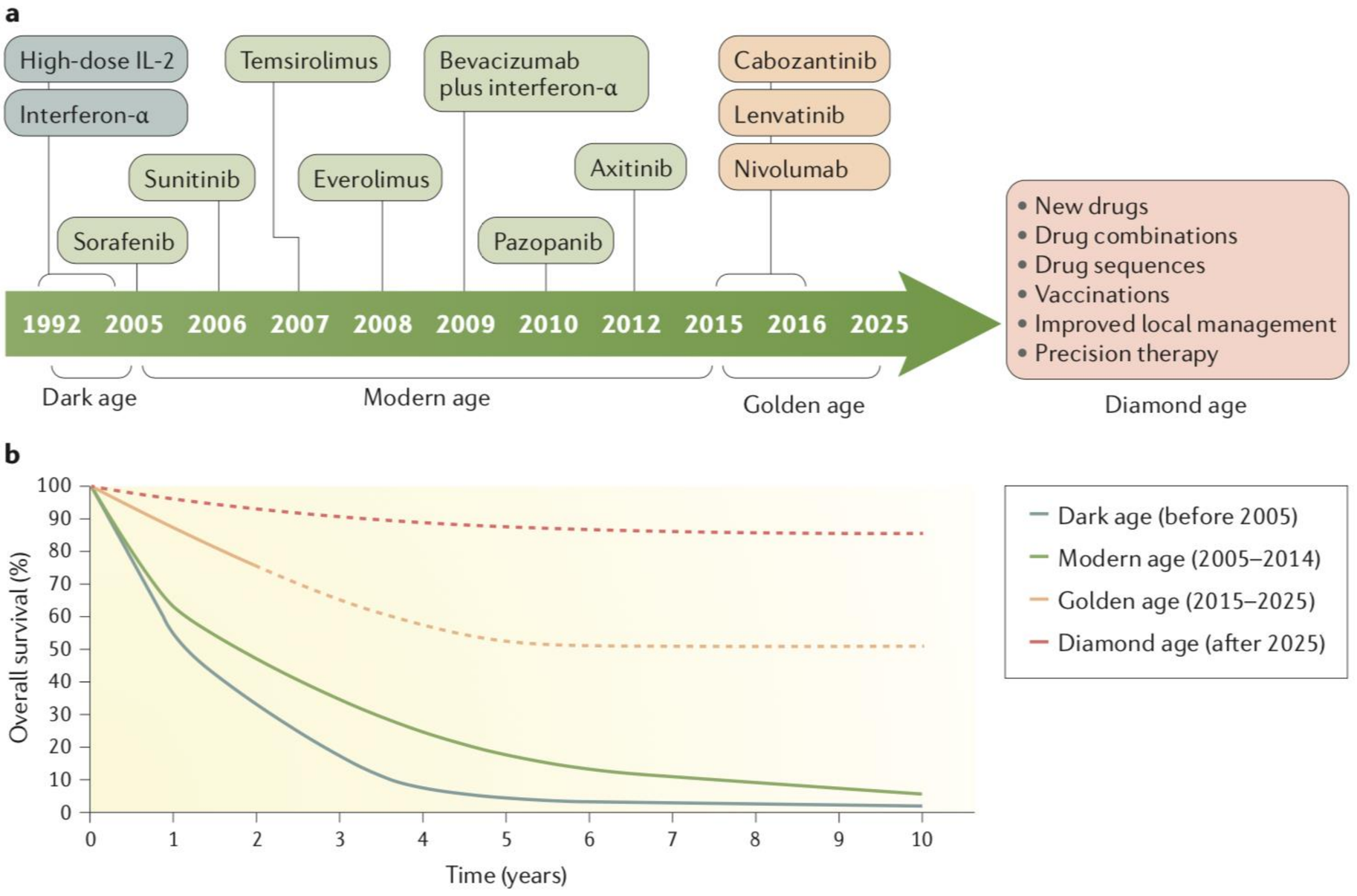
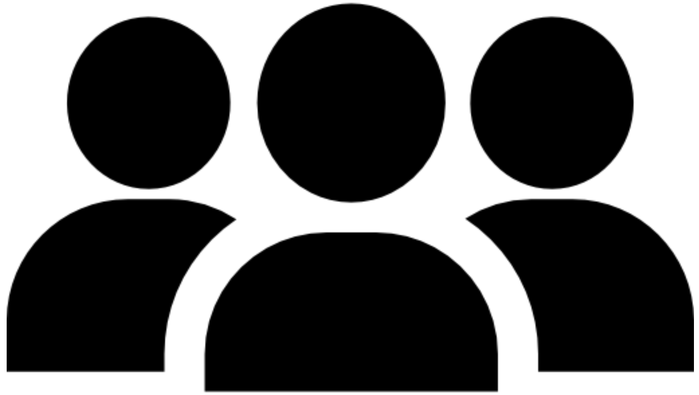


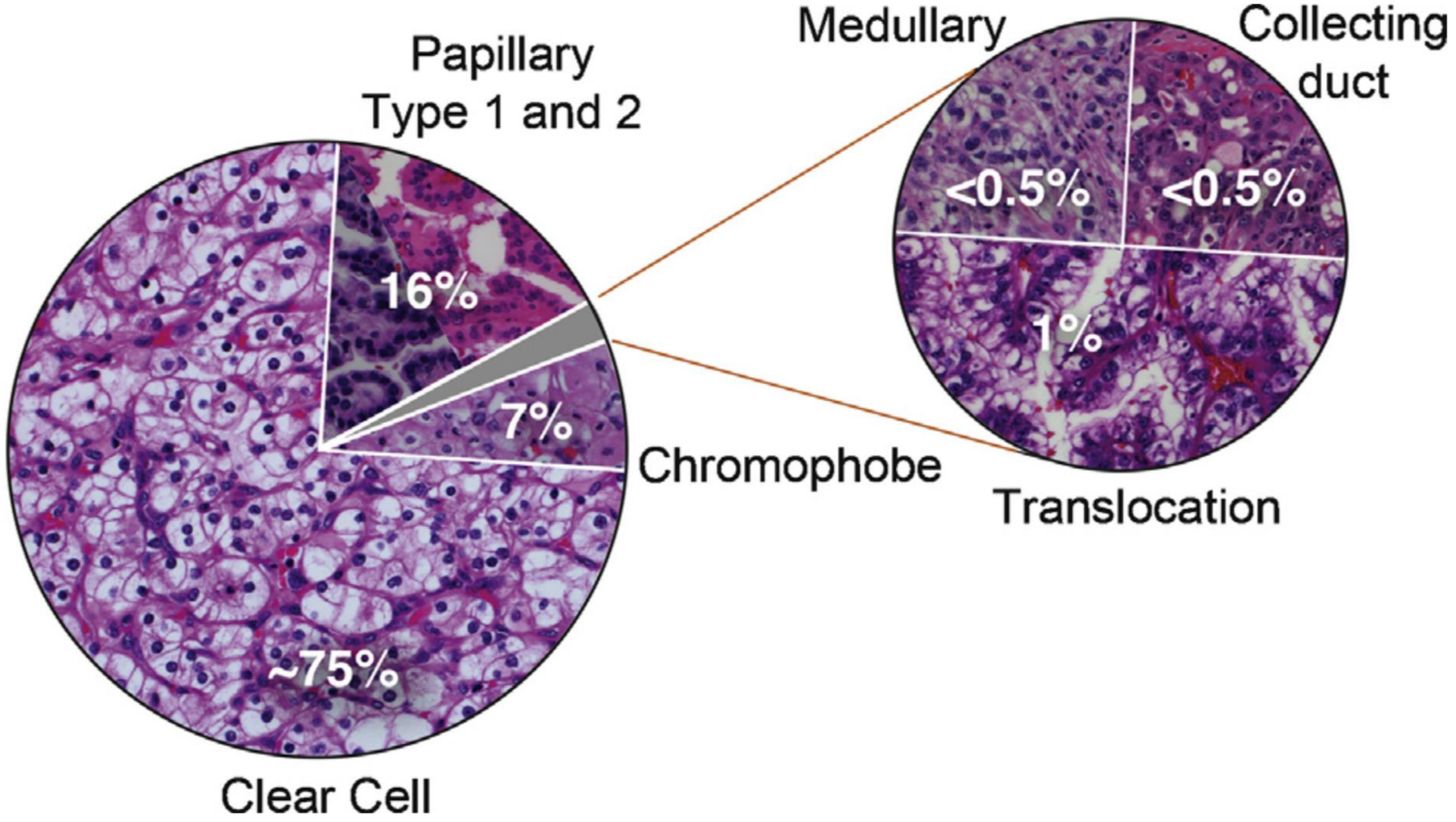
Figure 7 | **Therapeutic evolution and survival outcome of metastatic clear cell renal cell carcinoma through**

Histologías

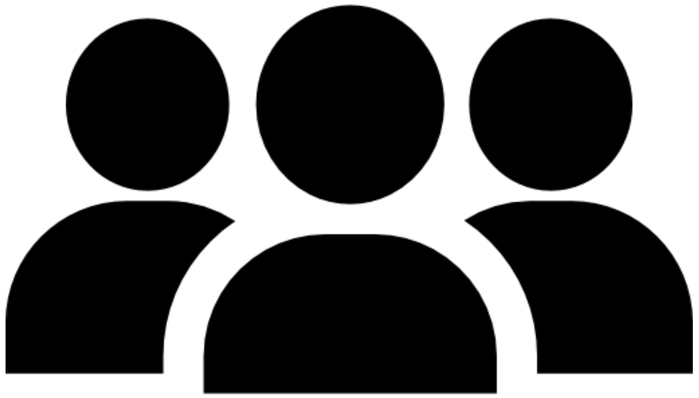


3 histologías mas frecuentes

Histologías



Genética:



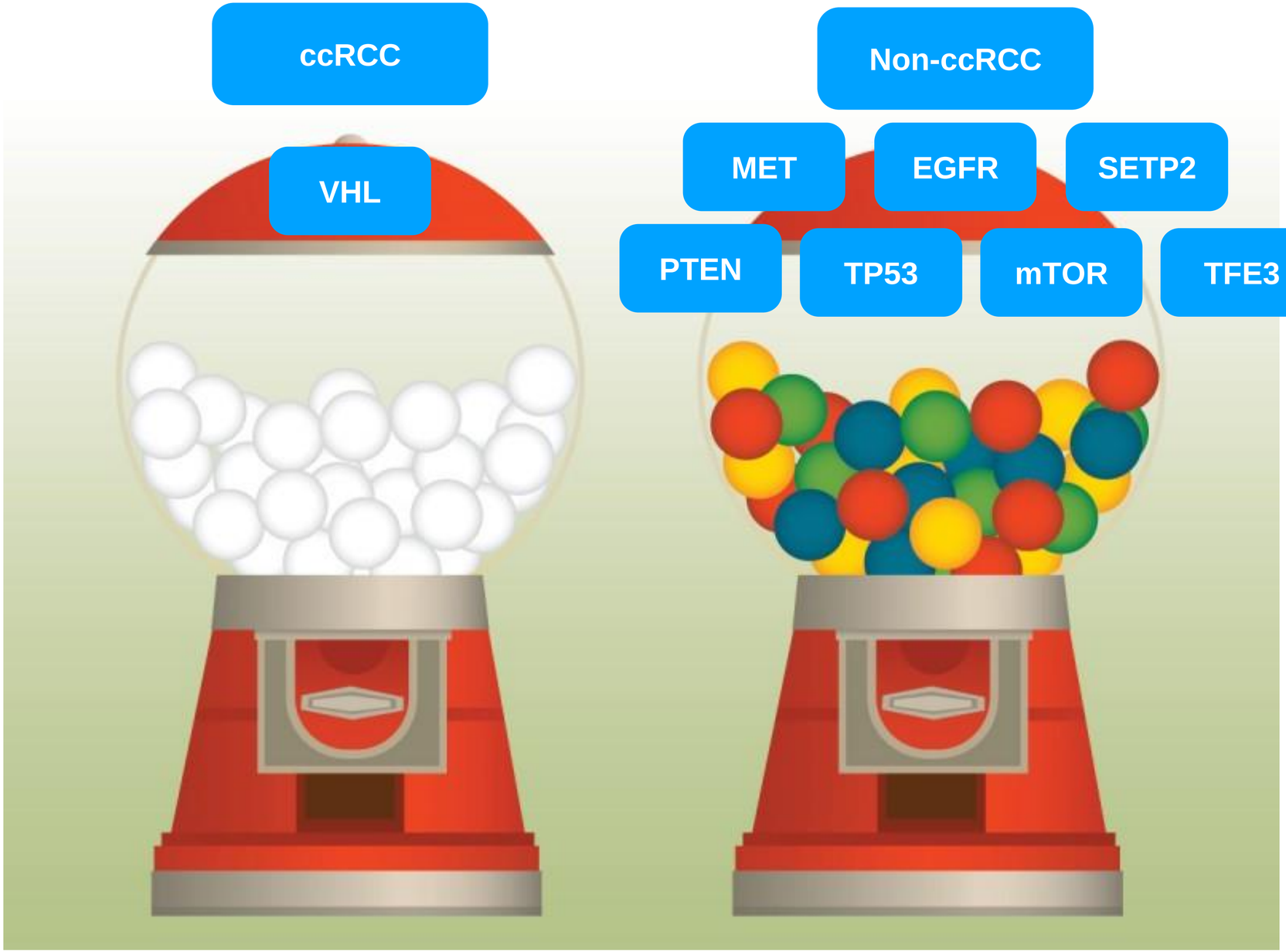
Alteración genética esporádica mas característica

Síndromes Genéticos

¿Que características individuales nos deben hacer sospechar?

¿Que características histológicas?

Histologías



NCCN Guidelines Version 3.2023
Hereditary Renal Cell Carcinoma

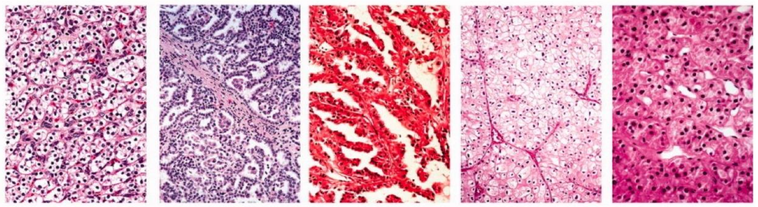
CRITERIA FOR FURTHER GENETIC RISK EVALUATION FOR HEREDITARY RCC SYNDROMES[a]

1. An individual with a close blood relative[b] with a known pathogenic/likely pathogenic variant in a cancer susceptibility gene
2. An individual with RCC with any of the following criteria:
▸ Diagnosed at age ≤46 y ▸ Bilateral or multifocal tumors ▸ ≥1 first- or second-degree relative[b] with RCC
3. An individual whose tumors have the following histologic characteristics:
▸ Multifocal papillary histology ▸ HLRCC-associated RCC, RCC with fumarate hydratase (FH) deficiency or other histologic features associated with HLRCC ▸ Birt-Hogg-Dubé syndrome (BHDS)-related histology (multiple chromophobe, oncocytoma, or oncocytic hybrid) ▸ Angiomyolipomas of the kidney and one additional tuberous sclerosis complex (TSC) criterion in the same person (See Table 1) ▸ Succinate dehydrogenase (SDH)-deficient RCC histology[e]
4. An unaffected individual[c,d] with any of the following criteria:
▸ ≥2 first- or second-degree relatives[b] with RCC (on the same side of the family) ▸ Any first degree relative who meets the criteria in boxes 2 and 3 who is unable or unwilling to genetically test

→ See GENE-1

→ Consider referral to cancer genetics professional and Refer to specific syndromes - See Hereditary RCC Syndromes Overview (HERED-RCC-2), See NCCN Guidelines for Genetic/ Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic: Principles of Cancer Risk Assessment and Counseling (EVAL-A) and Pedigree (EVAL-B)

Human Renal Epithelial Neoplasms



NCCN Guidelines Version 3.2023
Hereditary Renal Cell Carcinoma

HEREDITARY RCC SYNDROMES OVERVIEW

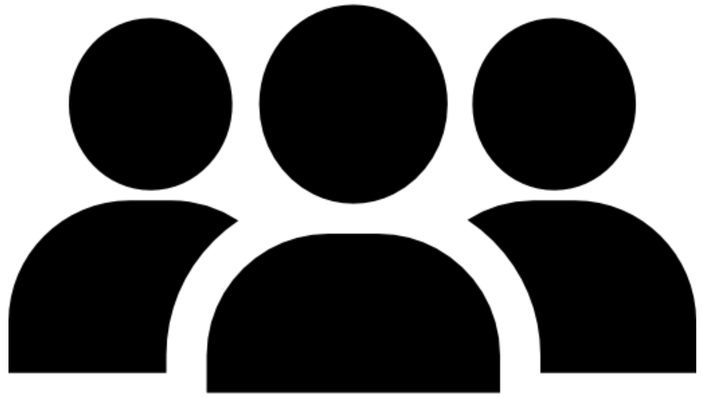
Syndrome/Gene	Common Histologies	Inheritance Pattern Major Clinical Manifestations	Other Specialists Involved in Screening
von Hippel-Lindau (VHL)/ *VHL* gene	Clear cell	• Autosomal dominant • See Table 2	• Neurosurgery • Ophthalmology • Audiology • Endocrinology • Endocrine surgery
Hereditary papillary renal carcinoma (HPRC)/*MET* gene	Type 1 papillary	• Autosomal dominant • Multifocal, bilateral renal cell tumors	• Nephrology
Birt-Hogg-Dubé syndrome (BHDS)/*FLCN* gene[1,2]	Chromophobe, hybrid oncocytic tumors, papillary RCC	• Autosomal dominant • Cutaneous fibrofolliculoma or trichodiscoma, pulmonary cysts, and spontaneous pneumothorax	• Pulmonology • Dermatology
Tuberous sclerosis complex (TSC)/*TSC1, TSC2* genes	Angiomyolipoma, clear cell	• Autosomal dominant • See Table 1	• Neurology • Dermatology
Hereditary leiomyomatosis and renal cell carcinoma (HLRCC)/*FH* gene	HLRCC or FH-associated RCC/ type 2 papillary	• Autosomal dominant • Leiomyomas of skin and uterus, unilateral, solitary, and aggressive renal cell tumors. PET-positive adrenal adenomas	• Gynecology • Dermatology
BAP1 tumor predisposition syndrome (TPDS)/*BAP1* gene[3,4]	Clear cell, chromophobe	• Autosomal dominant • Melanoma (uveal and cutaneous), kidney cancer, mesothelioma	• Dermatology • Ophthalmology • Thoracic oncology
Hereditary paraganglioma/ pheochromocytoma (PGL/ PCC) syndrome/*SDHA/B/ C/D* genes	Clear cell (not usually *SDHB*), chromophobe, papillary type 2, renal oncocytoma, oncocytic neoplasm	• Autosomal dominant • Head and neck PGL and adrenal or extra-adrenal PCCs, gastrointestinal stromal tumors (GISTs)	• Endocrine • Endocrine surgery

See GENE-1

[1] Schmidt LS, Nickerson ML, Warren MB, et al. Germline BHD-mutation spectrum and phenotype analysis of a large cohort of families with Birt-Hogg-Dubé syndrome. Am J Hum Genet 2005;76:1023-1033.
[2] Sattler EC, Steinlein OK. Birt-Hogg-Dubé Syndrome. 2006 Feb 27 [Updated 2020 Jan 30]. In: Adam MP, Ardinger HH, Pagon RA, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle;1993-2020.
[3] Peña-Llopis S, Vega-Rubín-de-Celis S, Liao A. BAP1 loss defines a new class of renal cell carcinoma. Nat Genet 2012;44:751-759.
[4] Hakimi AA, Ostrovnaya I, Reva B. Adverse outcomes in clear cell renal cell carcinoma with mutations of 3p21 epigenetic regulators BAP1 and SETD2: a report by MSKCC and the KIRC TCGA Research Network. Clin Cancer Res 2013;19:3259-3267.

Evaluación Diagnóstica

¿ Cómo llegan estos pacientes a consulta?



¿ Síntomas?

¿ Qué estudios se requieren?

Evaluación Diagnóstica

Síntomas: **Asintomáticas** !!!

- Dolor Lumbar
- Masa Palpable
- Hematuria

Enfermedad Avanzada

Evaluación Diagnóstica

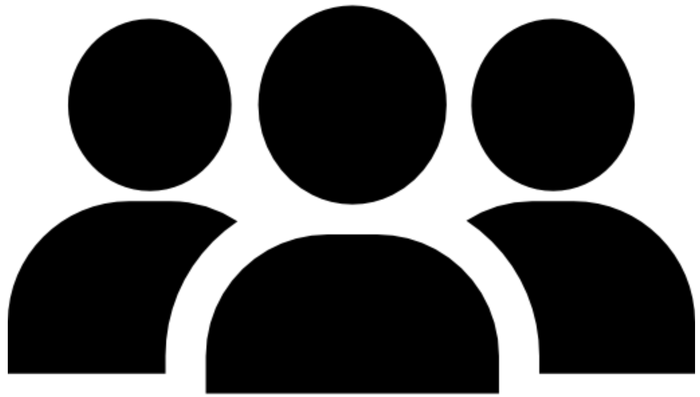
67 años

AP: Obeso, HTA, DLP, CI con stent 2017 a CD. Buena función VI.

ECOG: 0.

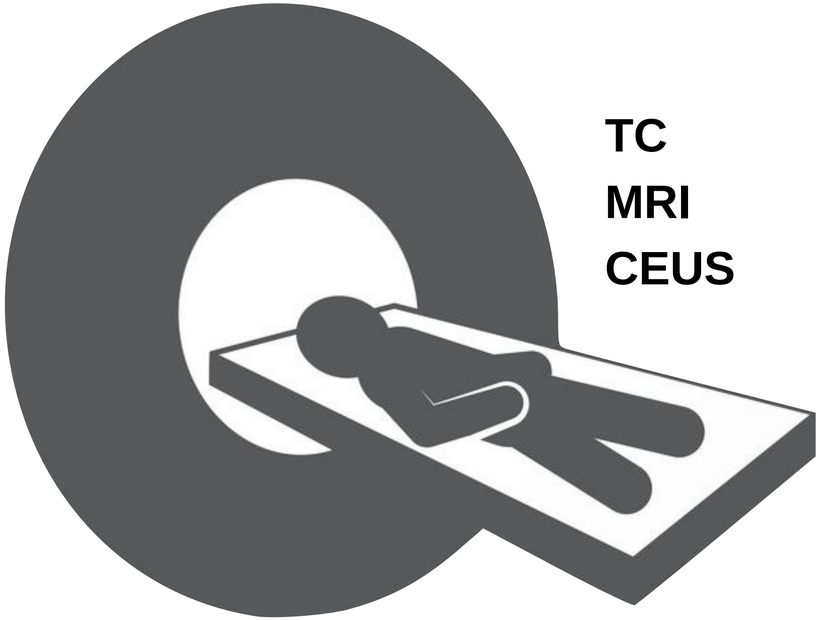
Eco: solicitada por MIN por alteracion habito intestinal aparece incidentalmente sospecha de masa solida renal izquierda de 4.5cm.

Evaluación Diagnóstica



Evaluación Diagnóstica

Técnicas de imagen en el diagnóstico de la mas renal



TC

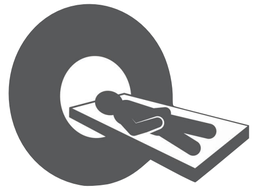
MRI

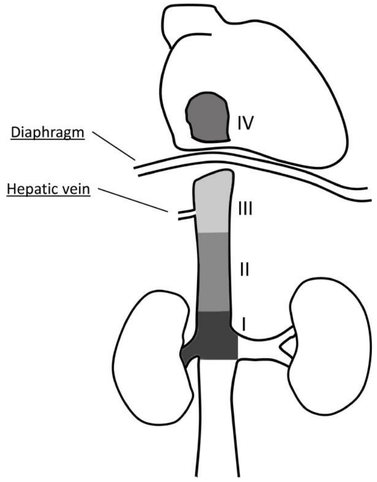
CEUS

TC multifásico

S: >90% (81-94%)
E: >85% (51-90%)

MRI

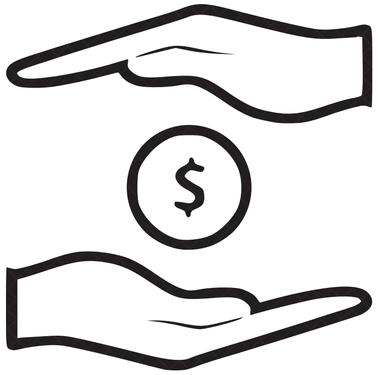




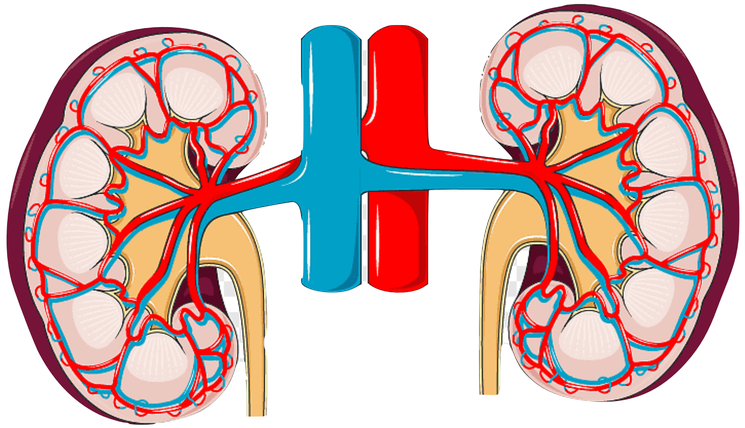
Útil para el **diagnóstico y el estadiaje completo.** GOLD STANDARD — Rápido

caracterizar el subtipo histológico,así como las características intrínsecas del tumor y el compromiso vascular, lo que tiene implicaciones pronósticas quirúrgicas..

Rápido



Barato



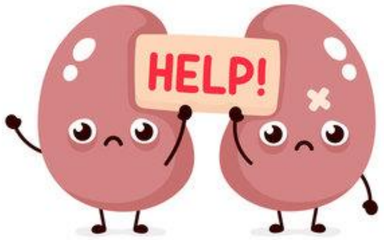
Estadiaje Local: T y N
Estadiaje Distancia
Compromiso Venoso
Fx Riñón Contralateral

Vogel C, Ziegelmüller B, Ljungberg B, Bensalah K, Bex A, Canfield S, Giles RH, Hora M, Kuczyk MA, Merseburger AS, Powles T, Albiges L, Stewart F, Volpe A, Graser A, Schlemmer M, Yuan C, Lam T, Staehler M. Imaging in Suspected Renal-Cell Carcinoma: System

TC multifásico

Útil para el [diagnóstico y el estadiaje completo.](#) GOLD STANDARD — Rápido

caracterizar el subtipo histológico,así como las características intrínsecas del tumor y el compromiso vascular, lo que tiene implicaciones pronósticas quirúrgicas..

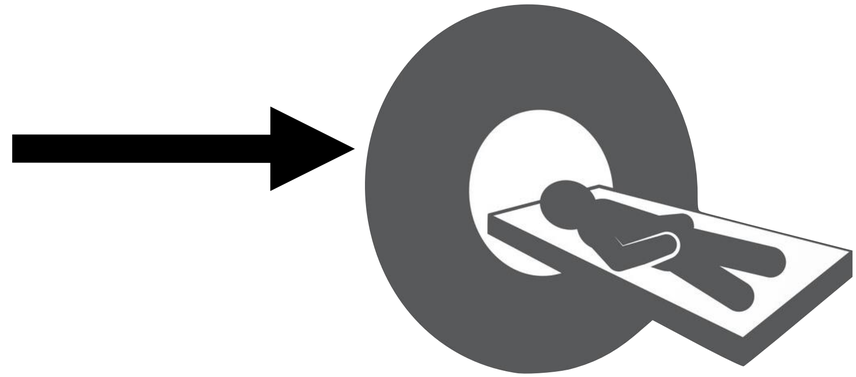


Insuficiencia renal

Alergia Contrastes

Pediatrica / Embarazo

MRI



Vogel C, Ziegelmüller B, Ljungberg B, Bensalah K, Bex A, Canfield S, Giles RH, Hora M, Kuczyk MA, Merseburger AS, Powles T, Albiges L, Stewart F, Volpe A, Graser A, Schlemmer M, Yuan C, Lam T, Staehler M. Imaging in Suspected Renal-Cell Carcinoma: System

TC multifásico

THE GOLD STANDARD

Masa Renal Indeterminada TC/RM
Quiste Complejo (Bosniak II-F- III)

CEUS

SENSIBILIDAD Y ESPECIFICIDAD
Comparable Con TC y RM

available at www.sciencedirect.com
journal homepage: euoncology.europeanurology.com

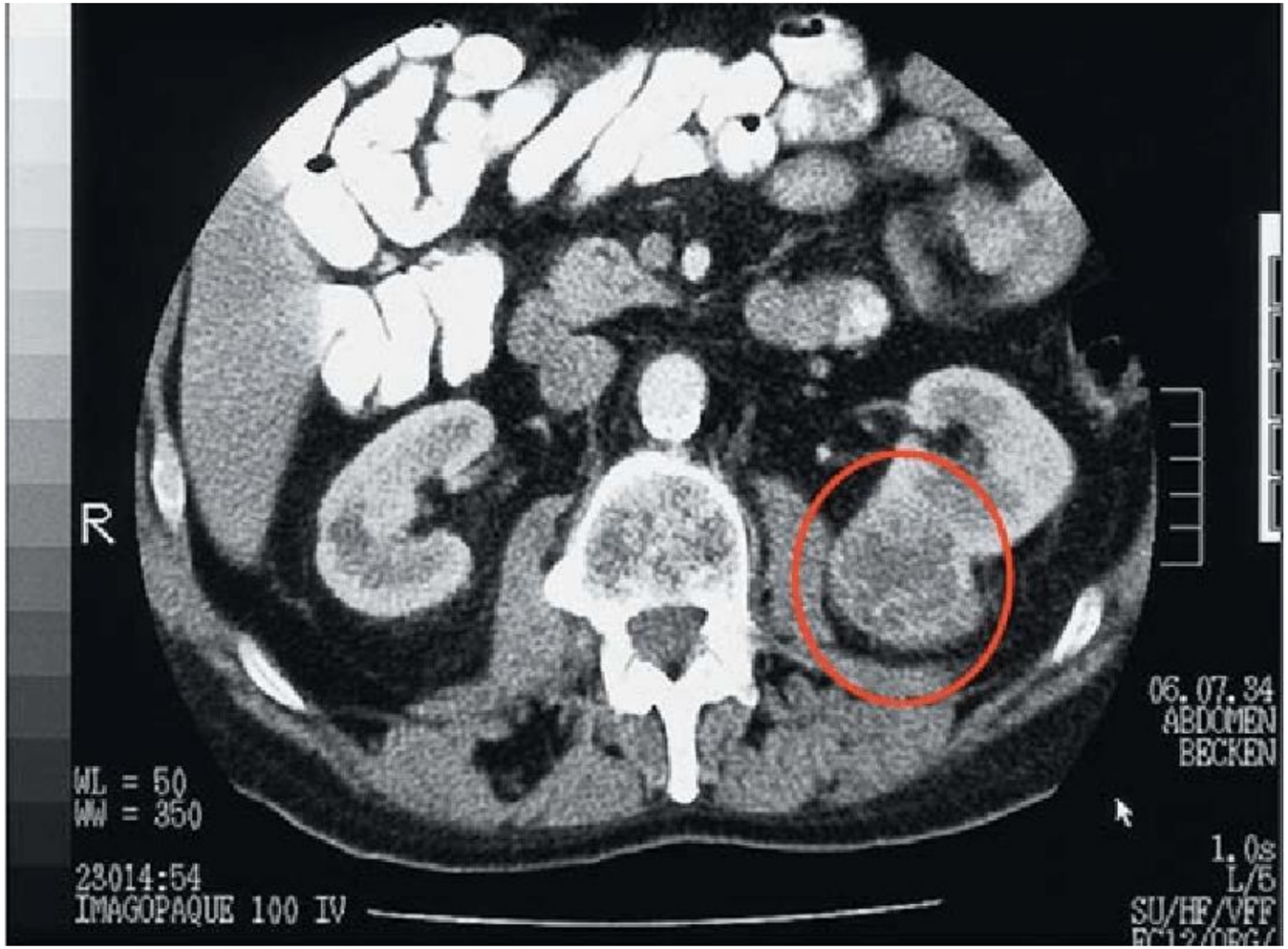
European Association of Urology

Comparison of the Diagnostic Performance of Contrast-enhanced Ultrasound with That of Contrast-enhanced Computed Tomography and Contrast-enhanced Magnetic Resonance Imaging in the Evaluation of Renal Masses: A Systematic Review and Meta-analysis

Marc A. Furrer [1,], Samuel C.J. Spycher [1], Sophia M. Büttiker [1], Tobias Gross, Piet Bosshard,*

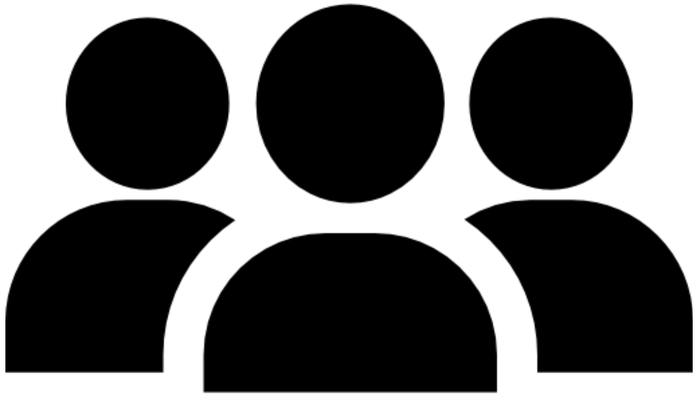
Furrer MA, Spycher SCJ, Büttiker SM, Gross T, Bosshard P, Thalmann GN, Schneider MP, Roth B. Comparison of the Diagnostic Performance of Contrast-enhanced Ultrasound with That of Contrast-enhanced Computed Tomography and Contrast-enhanced Magnetic Re

Evaluación Diagnóstica

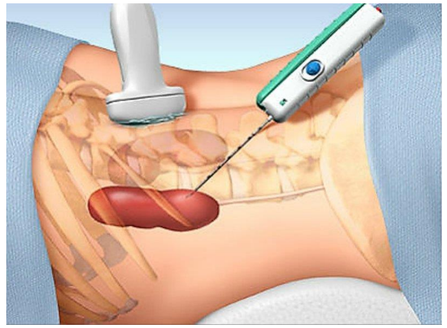


TC: Confirma naturaleza solida capta contraste 4.1cm diametro máximo . No lesiones a distancia. cT1bN0M0

Orientación Terapéutica

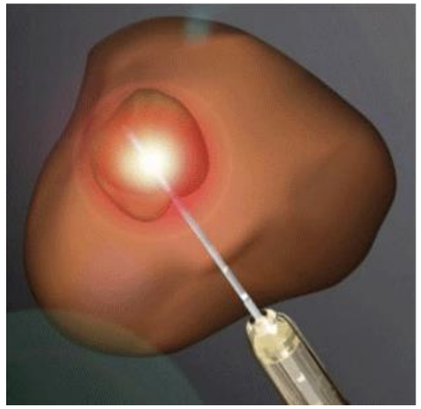


Evaluación Terapéutica



Biopsia

Cirugía

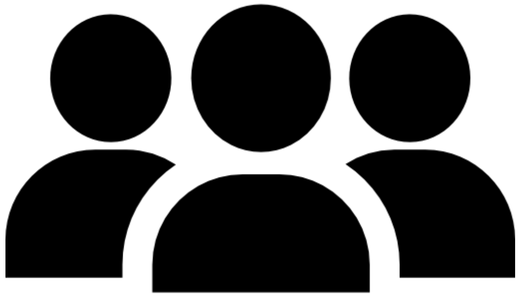


Tratamiento Focal

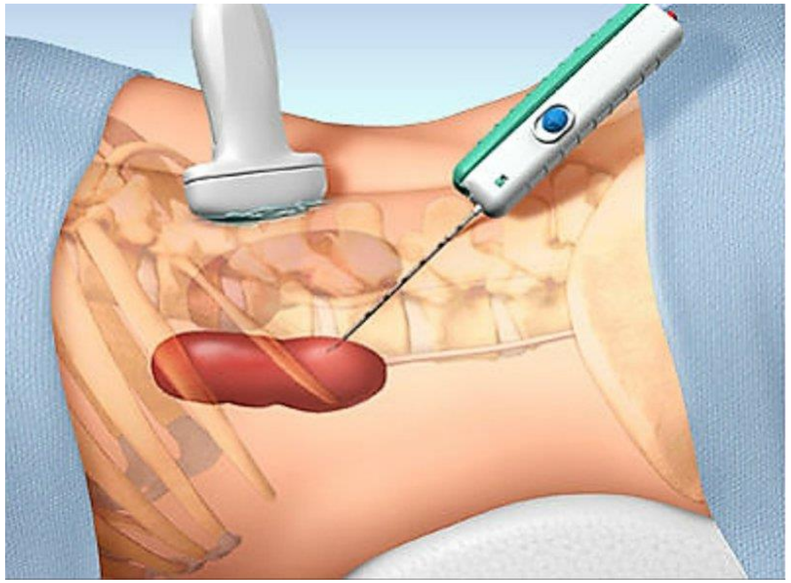
Biopsia SI/NO.

Opciones terapeuticas: NSS/RN/Focal Therapy/ SBRT

LND



Biopsia



TC RM CEUS Indeterminada

Vigilancia Activa
Previo Tratamiento Focal
M+

Vigilancia Expectante (comórbidos y frágiles)

Diagnóstico Radiologico —> Tratamiento radical (alta precisión pruebas imagen)

Masas quísticas (menor rendimiento y precisión diagnóstica. excepto si áreas con patrón sólido: **quistes Bosniak IV)**

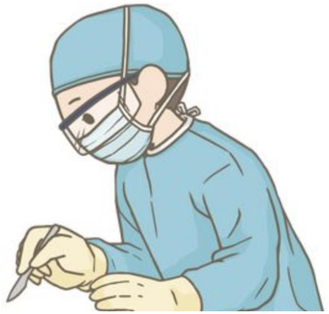
TRUCUT x2-3
S y E Malignidad > 99%
Precisión Histologica > 90%
Precisión Grado 62% (High - Low 85 %)

SEGURIDAD
Baja tasa de complicaciones

@PJimenezMarrero

Pablo Jiménez Marrero
Sep 2023

Opciones terapéuticas cáncer renal localizado

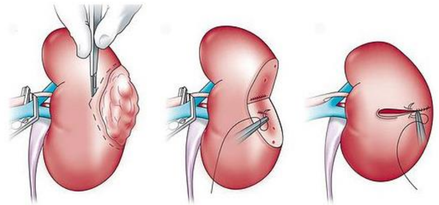


Tratamiento quirúrgico

(mortalidad cáncer específica significativamente menor)

Nefrectomía parcial (NP) Vs radical (NR):

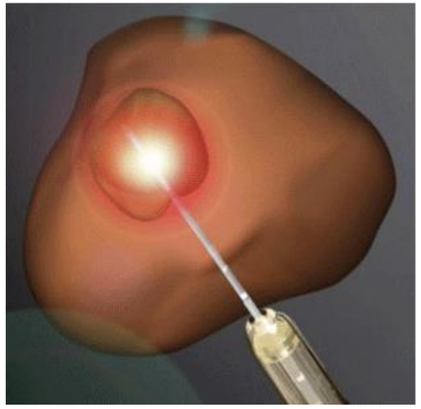
- NP DE ELECCIÓN en tumores T1 (también si ERC previa): preserva FR



** NR laparoscópica en tumores T2 y masas localizadas no tratables mediante NP
** NO se recomienda NR en tumores T1 si NP es factible por cualquier abordaje, **INCLUSO ABIERTO.**
** NO se recomienda NP si puede comprometer resultados oncológicos, funcionales y perioperatorios.

T2: Considerar NP si técnicamente factible, en monorenos, tumores bilaterales o ERC (con suficiente volumen parenquimatoso preservado que permita función renal postQx suficiente).

Evaluación Terapéutica



SBRT

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EUROPEAN UROLOGY xxx (2022) xxx

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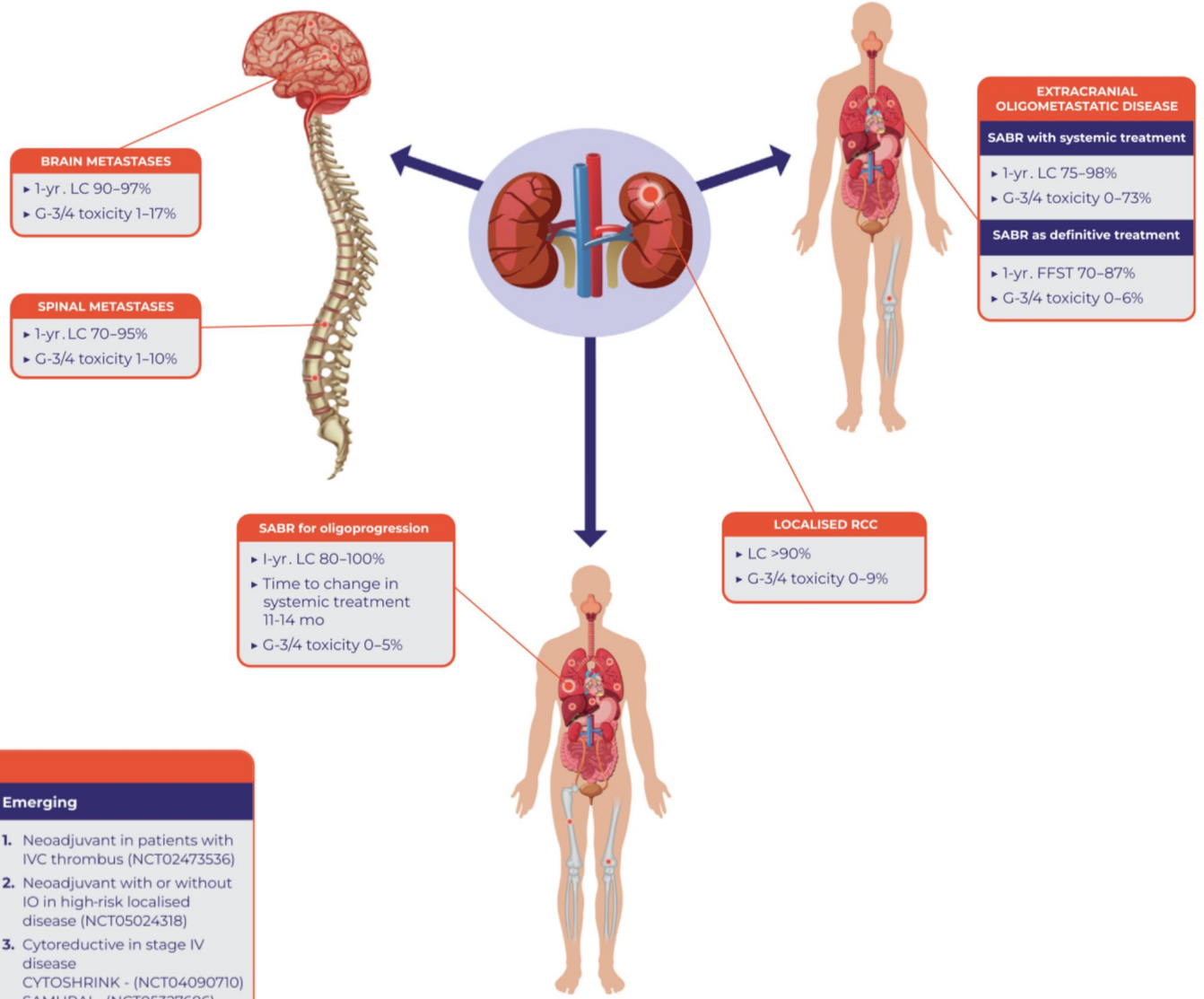
European Association of Urology

Platinum Priority – Review – Kidney Cancer
Editorial by XXX on pp. x-y of this issue

The Role of Stereotactic Ablative Body Radiotherapy in Renal Cell Carcinoma

Muhammad Ali [a,b,], Jennifer Mooi [c], Nathan Lawrentschuk [d,e,f], Rana R. McKay [g], Raquibul Hannan [h], Simon S. Lo [i], William A. Hall [j], Shankar Siva [a,b]*



INDICATIONS

Intracranial disease	Spinal disease	Primary RCC	Extracranial disease	Emerging
1. Postoperative 2. Definitive for 1-5 lesions 3. Progression after whole brain radiotherapy	1. Postoperative 2. Definitive to achieve local control 3. Palliative to improve pain	1. Medically inoperable 2. Technically challenging for other nephron-sparing options 3. Larger tumors (>3 cm) that are not ideal for TA 4. Salvage post NSS or TA	1. Selective patients with oligometastatic disease · Definitive to defer systemic treatment · In combination with systemic treatment to improve outcomes 2. Oligoprogression to delay systemic treatment switch	1. Neoadjuvant in patients with IVC thrombus (NCT02473536) 2. Neoadjuvant with or without IO in high-risk localised disease (NCT05024318) 3. Cytoreductive in stage IV disease CYTOSHRINK - (NCT04090710) SAMURAI - (NCT05327686)

Fig. 1 – Safety and efficacy of SABR in renal cell carcinoma. FFST = freedom from systemic therapy; G-3/4 = grade 3 and 4; IO = immunotherapy; IVC = inferior vena cava; LC = local control; NSS = nephron-sparing surgery; RCC = renal cell carcinoma; SABR = stereotactic ablative body radiotherapy; TA = thermal ablation.

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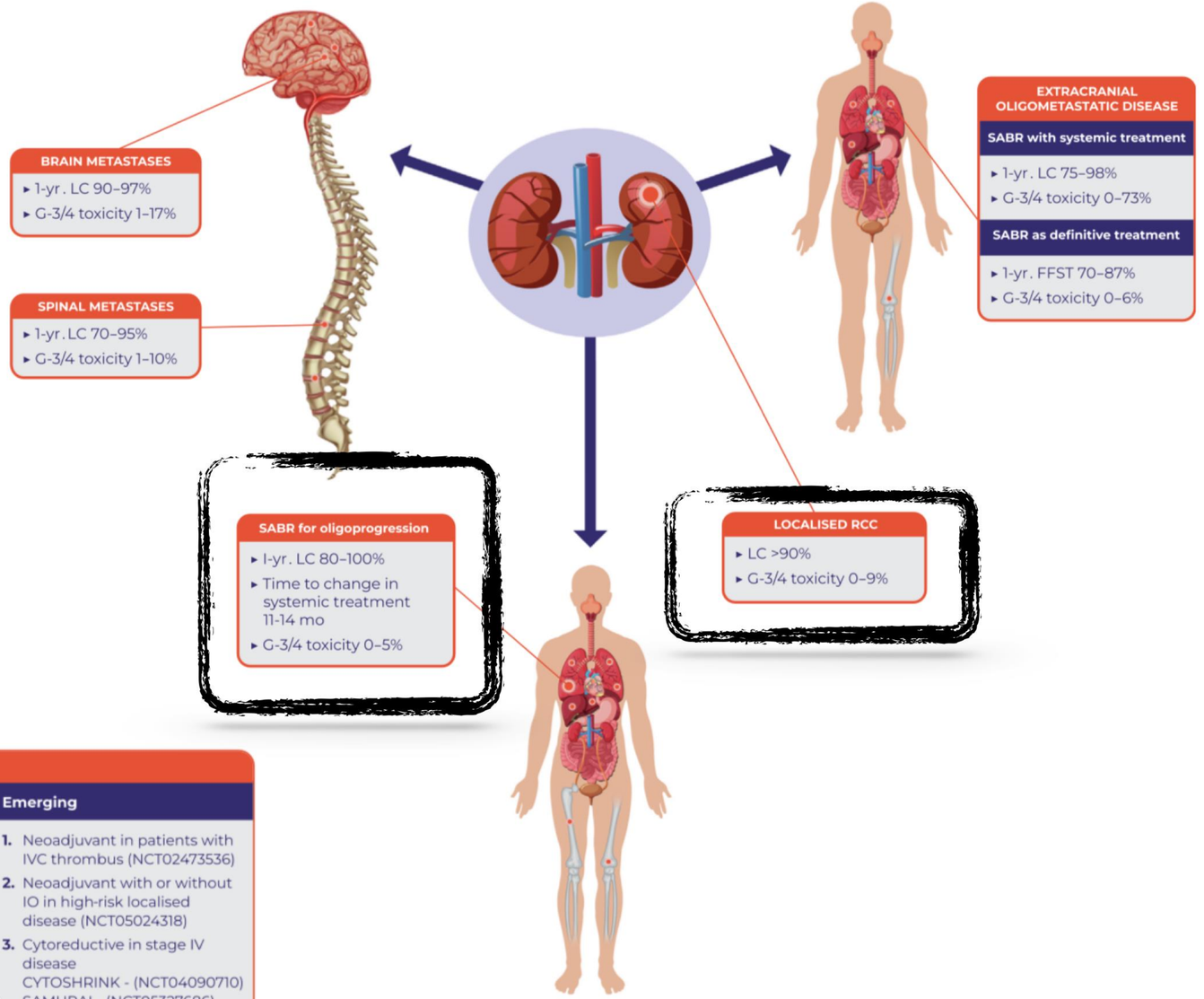

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Table 1 – SABR for primary RCC (inclusive of, and since the Correa et al. [5] meta-analyses)

Author (year)	Study type	Patients (*n*)	Tumour size[a]	Follow-up (mo)	Dose (Gy)/ fraction	Toxicity (grade 3/4)	LC (%)
Grelier et al. (2021) [14]	R	23	4.0 cm	22	35/5–7	0	96
Grubb et al. (2021) [17]	P	11	3.7 cm	34.3	48/3 54/3 60/3	9.1%	90
Swaminath et al. (2021) [16]	P	28	13 patients with ≤4 cm and 19 with >4 cm	NA	30–42/3–5	NA	NA
Margulis et al. (2021) [21][b]	P	6	NA	24	40/5	0	NA
Tetar et al. (2020) [13]	R	36	5.6 cm	16.4	40/5	0	95.2
Siva et al. (2020) [12]	R	95	4.9 cm	32.4	–	0	97.1
Senger et al. (2019) [15]	R	10	7 patients with T1a disease (size range 1.0–3.9 cm) and 3 patients with T3a disease (size range 0.9–7.0 cm)	27	24–25/1 36/3	0	92.3
Correa et al. (2019) [5]	MA	372	4.6 cm	28	26/1 30-40/3-5	1.5%	97.2

IVC-TT = tumour thrombus in the renal vein that can invade the inferior vena cava; LC = local control; MA = meta-analyses; NA = not available; P = prospective; R = retrospective; SABR = stereotactic ablative body radiotherapy.

[a] Median or mean.

[b] Neoadjuvant SABR for patients with IVC-TT (tumour thrombus).

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NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

Kidney Cancer

Version 3.2023 — September 22, 2022
https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf

Active Surveillance and Ablative Techniques

Active surveillance[74,75] is defined as the initial monitoring of tumors using abdominal imaging techniques with delayed intervention when indicated. Elderly patients and those with small renal masses (<2 cm) and other comorbidities often have low RCC-specific mortality.[76] Active surveillance and ablative techniques such as cryotherapy or radiofrequency ablation are alternative strategies for selected patients, particularly the elderly and those with competing health risks. Stereotactic body radiation therapy (SBRT) may be considered for medically inoperable patients with stage I kidney cancer (category 2B) and with stage II/II kidney cancer (category 3 for both.

https://uroweb.org/guidelines/renal-cell-carcinoma/chapter/disease-management

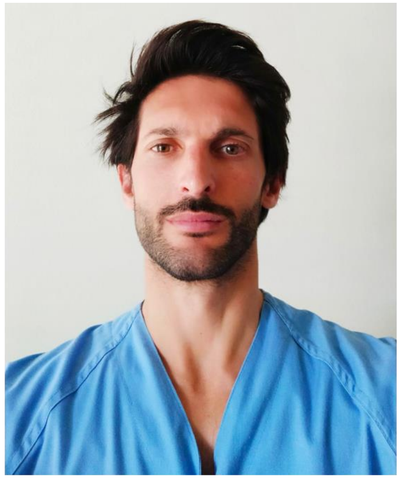
7.1.4.4.5. Stereotactic ablative radiotherapy

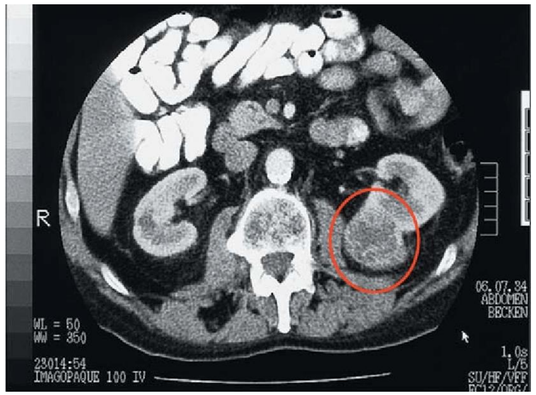
Stereotactic ablative radiotherapy (SABR) has been emerging as a treatment option for medically inoperable patients with localised cT1a and cT1b tumours. Patients usually receive 26 Gy in a single fraction, three fractions of 14 Gy or five fractions of 6 Gy [392,393]. In a systematic review or non-comparative single-arm studies, the local control rate was 97.2% and the mean change in eGFR was 7.7 mL/min/1.73 m2. Grade 3 or 4 toxicities occurred in 1.5% of patients. However, viable tumour cells are often seen in post-SABR biopsies, although their clinical significance remains unclear [393]. Although early results of SABR are encouraging, more evidence from randomised trials is needed.

Características del paciente para tratamiento con SBRT renal (tumor primário)

- Paciente inoperable, de alto riesgo quirúrgico/anestésico, o que rechaza cirugía.
- Filtrado glomerular >30 ml/min
- Tumor < 10 cm

Tratamiento:





Cirugía

ccRCC T3aN1 ISUP 3
R0

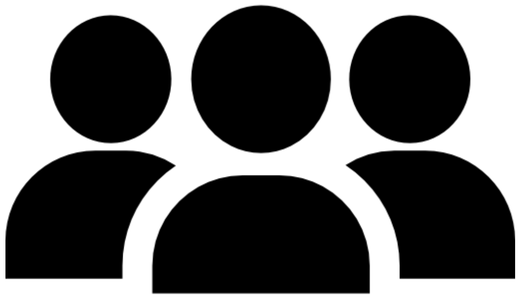
Tratamiento:

ccRCC T3aN1 ISUP 3
R0

¿Hay cabida para la Neoadyuvancia ?

¿Con estos resultados esta indicada la Adyuvancia?

¿Radioterapia lecho?



Tratamiento:

Tratamiento:

¿Hay cabida para la Neoadyuvancia ?

¿Con estos resultados esta indicada la Adyuvancia?

¿Radioterapia lecho?

Trials of Tyrosine Kinase Inhibitors as Adjuvant Treatment in RCC

Trial	Therapy	N	Histology	Stage	Starting Dose	Minimum Dose	Significant Difference?	
							DFS	OS*
ASSURE[1]	Sunitinib Sorafenib Placebo	1943	79% ccRCC ccRCC was Primary endpt	> pT1b, G3-4, or N+	50 or 37.5 mg (Su)/ 400 mg (So)	25 mg (Su)/40 mg (So)	No	No
S-TRAC[2,3]	Sunitinib Placebo	615	ccRCC	> pT3b or N+	**50 mg**	**37.5 mg**	Yes	No
PROTECT[4,5]	Pazopanib Placebo	1538	ccRCC or mostly ccRCC	pT2 (G3-4), ≥ pT3, or N+	600 mg	400 mg	No	No
ATLAS[1]	Axitinib Placebo	724	ccRCC	≥pT2 and/or N+, any Fuhrman grade (FG),	5 mg twice daily	1mg twice daily	No	No
SORCE[2]	Sorafenib Placebo	1711	84% had clear cell histology ccRCC and noncc	intermediate (score, 3-5) or high risk (score, 6-11) of relapse as per the Leibovich risk model	400mg twice daily or 400mg daily	400mg EOD	No	No

*Studies included OS as secondary endpoint and may not be powered to show an improvement.

1. Haas. Lancet. 2016;387:2008. 2. Ravaud. NEJM. 2016;375:2246. 3. Motzer. Eur Urol. 2018;73:62.
4. Motzer. JCO. 2017;35:3916. 5. Motzer. Eur Urol. 2021;79:334.

Adjuvant ICI studies in RCC

Trial	Sample Size	Inclusion Criteria	Treatment	Duration	Primary Endpoint	Expected Results
Keynote-564	994	pT2G4, pT3aG3-4, pT3b-T4Gx, pTxN1, pTxNxM1 (resected to NED within 1 year); clear cell	Pembrolizumab vs placebo	12 months	DFS	**Published**
IMmotion010	778	pT2G4, pT3aG3-4, pT3b-T4Gx, pTxN1, pTxNxM1 (resected to NED*); clear cell	Atezolizumab vs. placebo	12 months	DFS	Soon
CheckMate-914	1600	pT2aG3-4N0, pT2b-T4GxN0, pTxGxN1; clear cell	Nivolumab + ipilimumab vs. nivolumab + placebo vs. placebo	*6 months*	DFS	1/2023
Prosper	766	T2Nx, TxN1, TxNxM1 (resected to NED); any RCC histology	Nivolumab vs. active monitoring	10 doses total (1 preop)	EFS	Closed for futility
RAMPART	1750	Leibovich score 3-11; any RCC histology	Durvalumab + tremelimumab vs. durvalumab vs. active monitoring	12 months	DFS, OS	7/2024

*Metachronous pulmonary, lymph node, or soft tissue recurrence >12 months from nephrectomy; CPI=Checkpoint inhibitors; RCC=Renal cell carcinoma; NED=No evidence of disease; DFS=Disease-free survival; EFS=Event-free survival; OS=Overall survival.

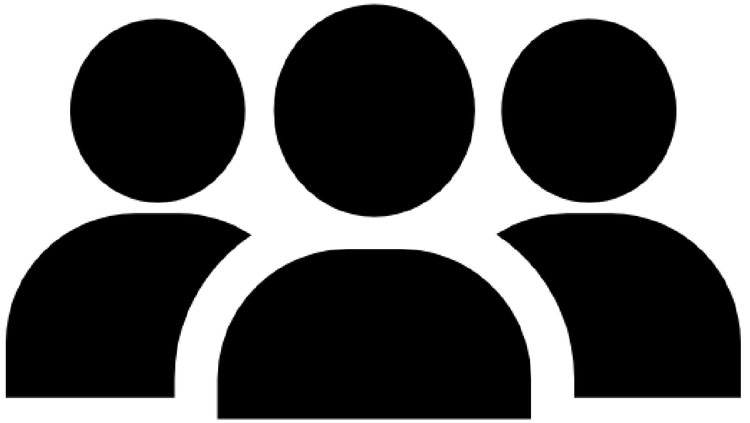

NEXT
STORY

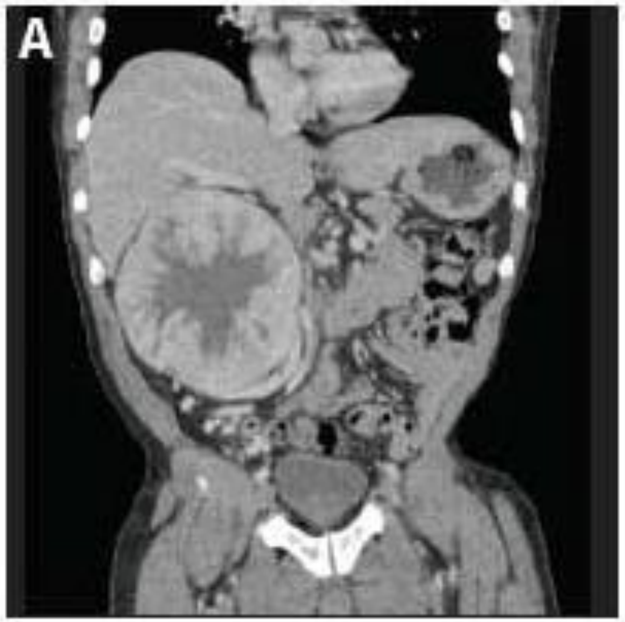
73 años.

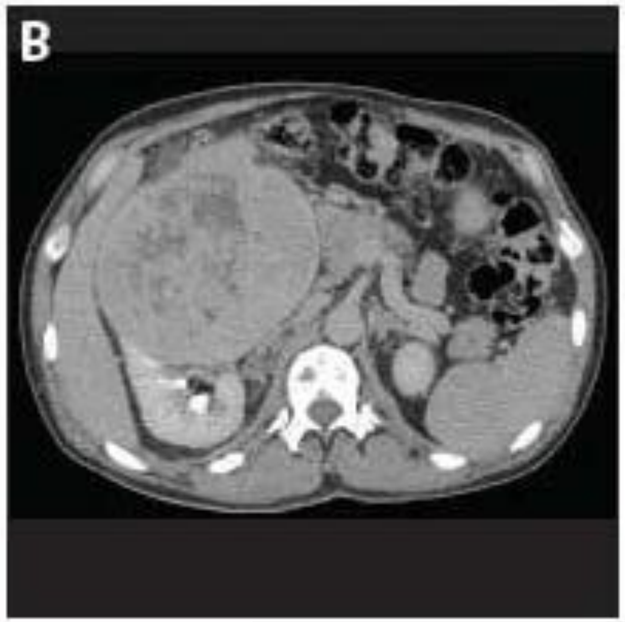
AP: HTA, DLP, CI con stent 2017 a CD. Buena función VI.

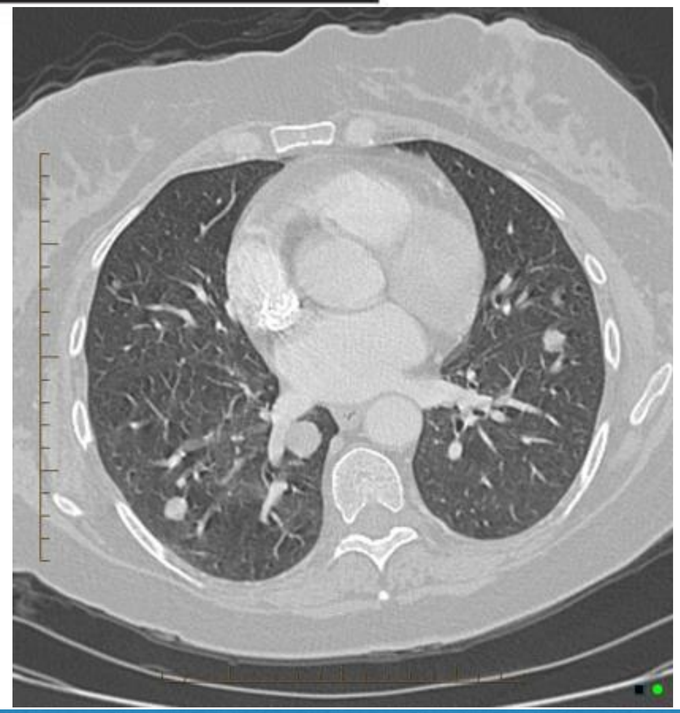
ECOG: 0.

Eco solicitada dolor lumbar y microhematuria aparece incidentalmente sospecha de masa solida renal izquierda de 8cm.





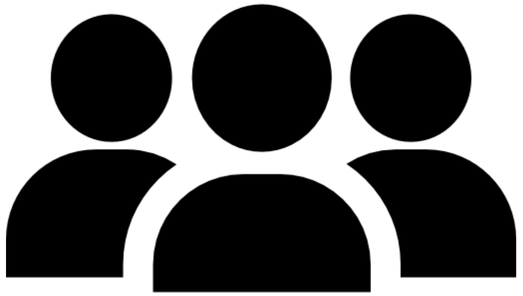


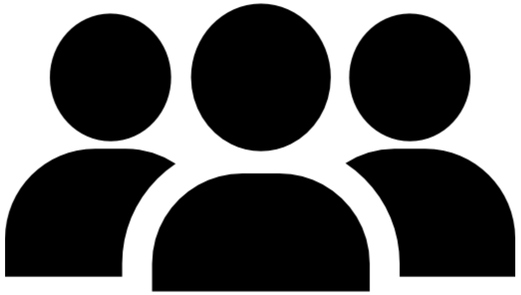


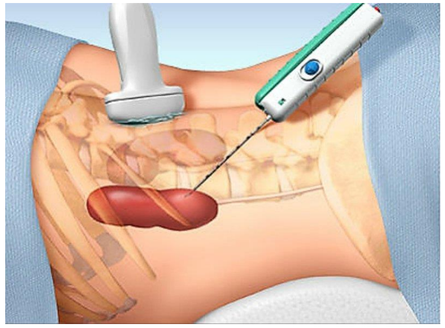
TC: Masa renal derecha sospechosa. 6 lesiones pulmonares

T3bN0M1

Analítica Normal







Biopsia

Cirugía

Tratamiento Sistemico

Understanding IMDC Criteria for Metastatic RCC

(Heng criteria)

Step 1

Before treatment

		Yes (1) / No (0)
Time from initial diagnosis to treatment	< 1 Year	1 / 0
+		
Karnofsky Performance Score (KPS)	< 80%	1 / 0
+		
Low Hemoglobin	< LLN	1 / 0
+		
High Calcium	> 10mg/dL	1 / 0
+		
High Platelet	> ULN	1 / 0
+		
High Neutrophil	> ULN	1 / 0
= Total		

Step 2

Risk Categories

Favourable Risk	▶ 0
Intermediate Risk	▶ 1 -2
Poor Risk	▶ ≥ 3

Step 3

Treatment Selection

Understanding IMDC Criteria for Metastatic RCC

(Heng criteria)

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		= Total

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Risk Categories

Favourable Risk	▶ 0
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Poor Risk	▶ ≥ 3

Step 3

Treatment Selection

Evaluación Terapéutica

¿Citoreducción / Nefrectomía Consolidación ?

¿Metastasectomía?

Tratamiento sistémico

Tratamiento local del CCR avanzado/metastásico

Nefrectomía citorreductora

Categoría de riesgo: favorable, intermedio o desfavorable

** 2 modelos pronósticos: MSKCC y Heng (IMDC)

IMDC:

- Karnofsky <80
- Inicio de tto sistémico <1 año desde el diagnóstico
- Calcio ↑
- Hb ↓
- Neutrófilos ↑
- Plaquetas ↑

0 factores: riesgo favorable
1 o 2 factores: riesgo intermedio
3 a 6 factores: riesgo desfavorable

- CARMENA y SURTIME
- **NO realizar nefrectomía citorreductora en pacientes de alto riesgo (desfavorable)**
- Se recomienda si: R. Intermedio (1 FR), Sintomas, Trombo tumoral.
- Otros factores: buen ECOG, tumores primarios grandes y volúmenes limitados de enfermedad metastásica.

Tratamiento local del CCR avanzado/metastásico

Papel de la metastasectomía

- Beneficio de la metastasectomía completa en términos de SG y SCE.

- Tratamiento local más apropiado para la mayoría de metástasis, excepto **cerebrales y óseas** —> mayor beneficio de la RT para control local sintomático y paliativo.

- Pacientes candidatos: enfermedad metastásica resecable aislada, con largo intervalo libre de enfermedad y buen PS.


PROS
CONS
•Alivio Sintomático
• Eliminar Potencial
fuente de Mts
• Activación de respuesta
• Mejora Supervivencia
• Potencial tratamiento
Curativo R0 vs Regresión
• Farmacodinámica
•Riesgo Quirúrgico
• Complicaciones Periop
• Retraso terapia sistémica

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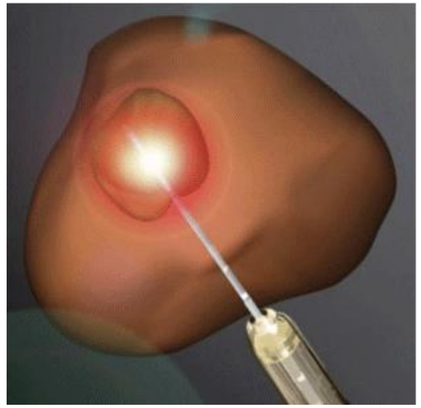
Step 3

Treatment Selection

Evaluación Terapéutica



SBRT
Metastasis

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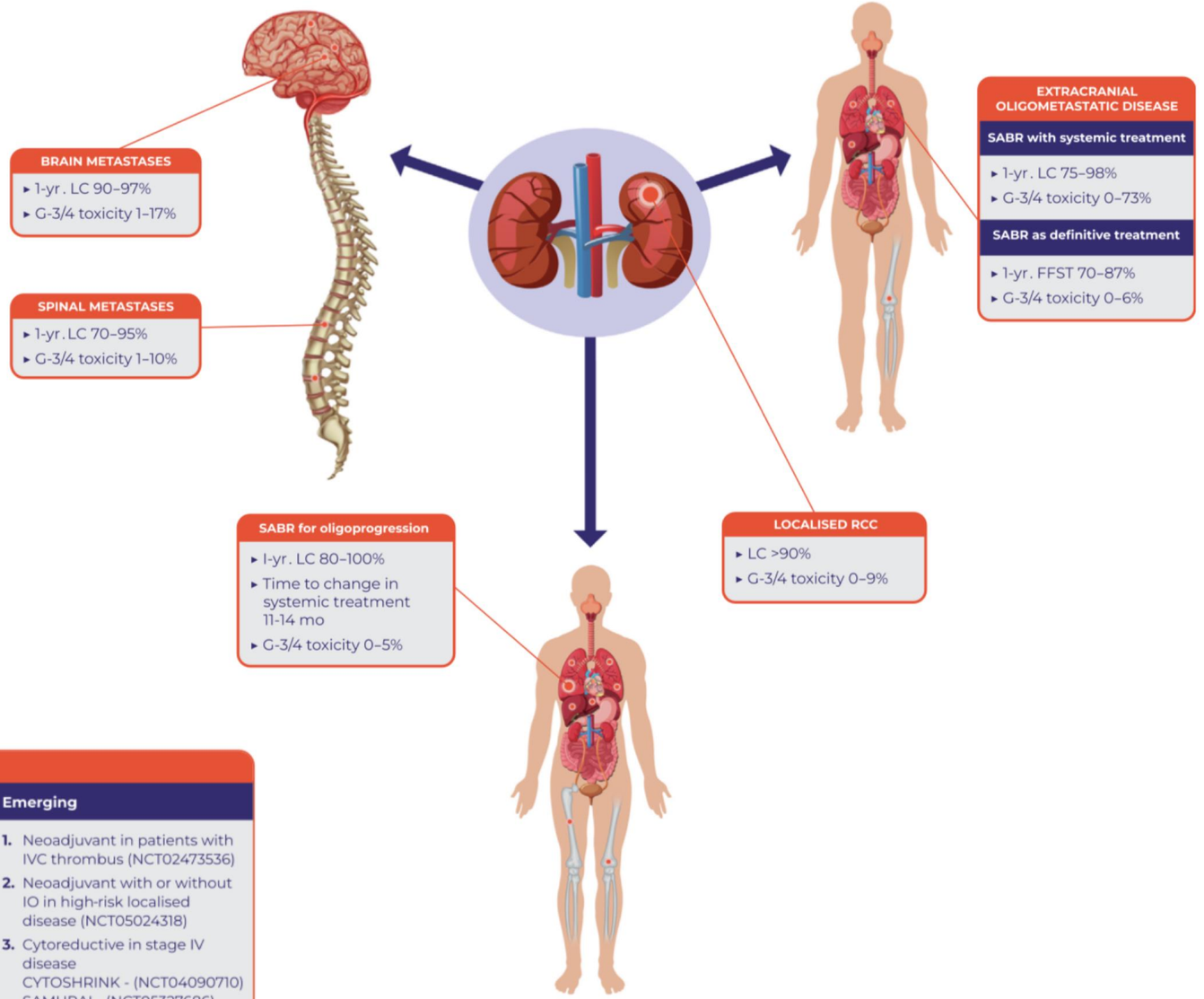

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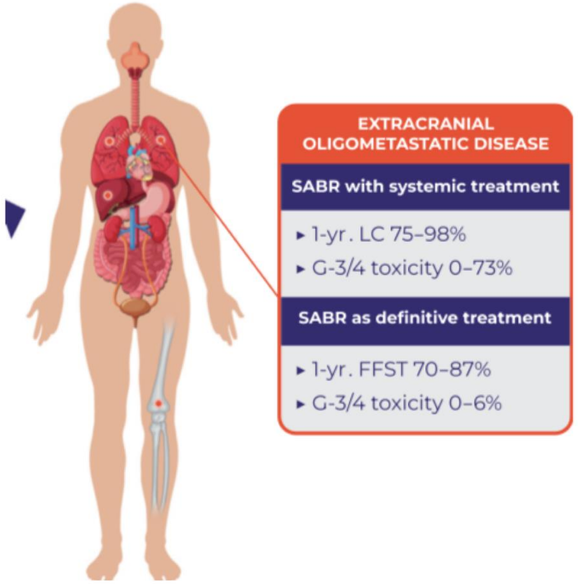
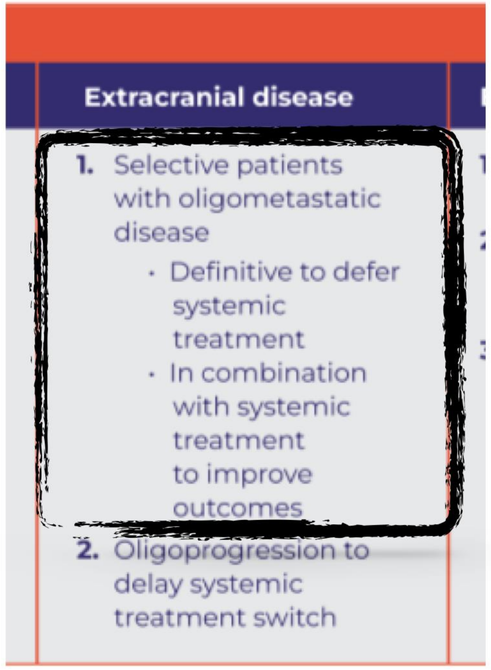


Table 3 – SABR in lieu of systemic treatment for oligometastatic RCC (since the Zaorsky et al. [6] meta-analyses)

Author (year)	Study type	Patients (*n*)	Site of disease (%)	Radiation dose	Toxicity (grade 3/4)	1-yr FFST (%)	1-yr OS (%)
Tang et al. (2021) [35]	P	30	Lung (57) Bone (17) Nodes (11) Other (15)	Most common 50 Gy in 4 fractions	6%/3%	82	100
Hannan et al, (2021) [34]	P	23	Total 57 sites	≥25 Gy × 1 fraction, ≥12 Gy × 3 fractions, or ≥8 Gy × 5 fractions	0	91.3	95
Chalkidou et al. (2021) [37]	P	143[a]	Most common site lung	NR	<5%[b]	NR	95.3
Marvaso et al. (2021) [36]	R	61	Bone (43) Lung (15) Liver (9) Soft tissue (9) Other (24)	Median 25 Gy in 5–10 fractions	0	70	78
Zhang et al. (2019) [33]	R	47	Bone (34) Lung (30) Brain (12) Nodes (8) Other (16)	18–26 Gy/1 fraction 36–42 Gy/3–5 fractions	0	Median 15.2 mo	93.1

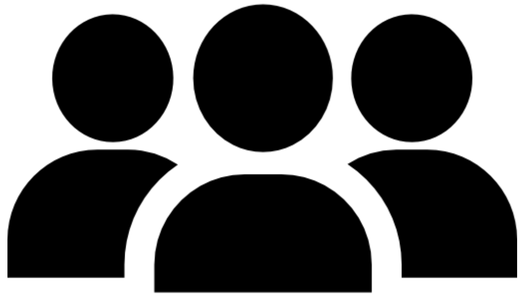
FFST = freedom from systemic therapy; NR = not reported; OS = overall survival; P = prospective; R = retrospective; RCC = renal cell carcinoma; SABR = stereotactic ablative body radiotherapy.
[a] A total of 143 renal cell carcinoma patients (total 1422 patients with different tumour histologies).
[b] Toxicity for all 1422 patients.



These results suggest that SABR might facilitate deferral of systemic treatment in carefully selected OM RCC patients without compromising OS and maintaining QOL. Before implementing this approach outside clinical trials, clinicians need to acknowledge the limitations of short follow-up, single-arm noncomparative design, and relatively novel nature of freedom from systemic treatment as an endpoint. Future areas of investigation should focus on long-term safety/outcomes of this approach, appropriate clinical/biomarkers for better selection of patients, and dose fractionation schedules for SABR.

Eur Urol (2022). https://doi.org/10.1016/j.eururo.2022.06.017

Tratamiento Sistémico:



Tratamiento Sistemico:

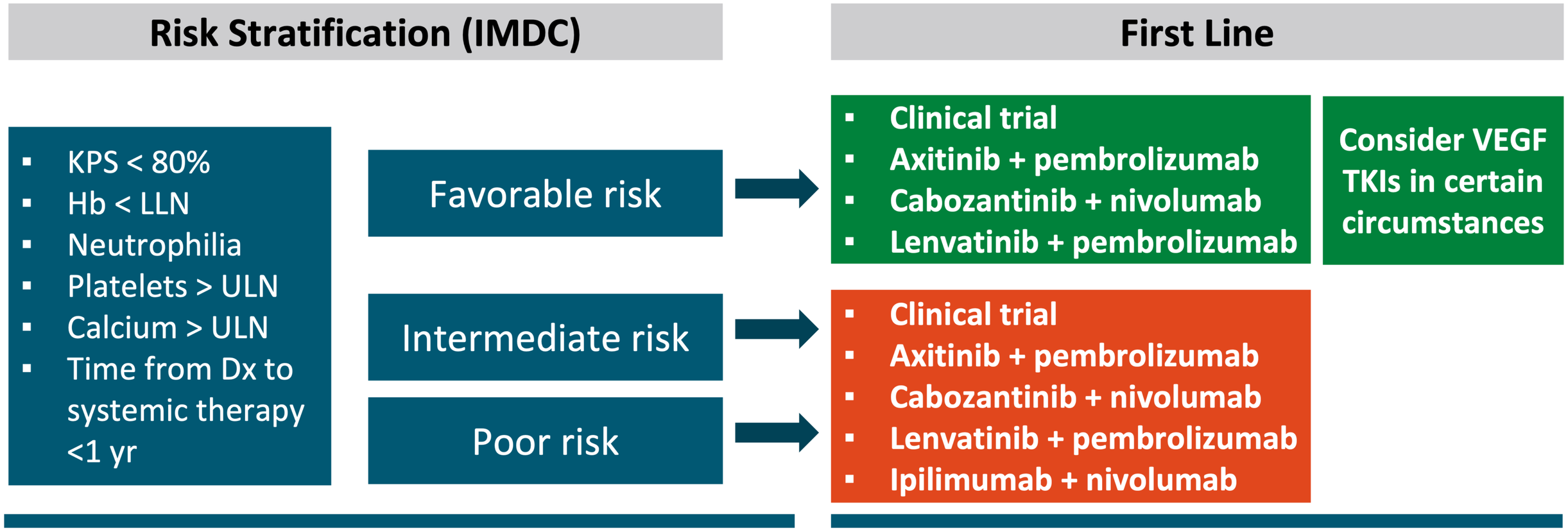
Opciones Terapeúticas

¿Cual y porque?

Perfiles

Respuestas

Current Therapeutic Landscape Advanced Renal Cell Carcinoma: First-line Therapy



NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer, Version 2.2023.

NCCN Guidelines Version 3.2023 Kidney Cancer

National Comprehensive Cancer Network®

NCCN Guidelines Version 3.2023
Kidney Cancer

NCCN Guideline
Table of C
Disc

PRINCIPLES OF SYSTEMIC THERAPY FOR RELAPSE OR STAGE IV DISEASE

FIRST-LINE THERAPY FOR CLEAR CELL HISTOLOGY

Risk	Preferred Regimens	Other Recommended Regimens	Useful in Certain Circumstances
Favorable[a]	• Axitinib + pembrolizumab[b] (category 1) • Cabozantinib + nivolumab[b] (category 1) • Lenvatinib + pembrolizumab[b] (category 1)	• Axitinib + avelumab[b] • Cabozantinib (category 2B) • Ipilimumab + nivolumab[b] • Pazopanib • Sunitinib	• Active surveillance[c] • Axitinib (category 2B) • High-dose IL-2[d] (category 2B)
Poor/ intermediate[a]	• Axitinib + pembrolizumab[b] (category 1) • Cabozantinib + nivolumab[b] (category 1) • Ipilimumab + nivolumab[b] (category 1) • Lenvatinib + pembrolizumab[b] (category 1) • Cabozantinib	• Axitinib + avelumab[b] • Pazopanib • Sunitinib	• Axitinib (category 2B) • High-dose IL-2[d] (category 3) • Temsirolimus[e] (category 3)

a See Risk Models to Direct Treatment (IMDC criteriA or MSKCC Prognostic Model) (KID-D)
b See NCCN Guidelines for Management of Inmunotherapy-Related Toxicities
c Rini BI, et al. 2016 Lancet Oncol 17:1317-1324
d Patients with excellent performance status and normal organ function.
e The poor risk model used in the global ARCC trial to direct treatment with tensirolimus. Hudes G, et al. 2007 N Engl J Med; 356:2271-2281.
f An FDA approved biosimilar is an apporpiate substitution for bevacizumab
g For patients who received >= 2 prior systemic therapies
Note: All recommendations are category 2A unless otherwise indicated
Clinical trials: NCCN believes that the best managment of any patient with cancer is in a clinical trial. Participation in clinical trials is especially encouraged
National Comprehensive Cancer Network. (2019). Kidney Cancer (version 2.2021).

Tratamiento Sistemico:

Disponibilidad

Precios rembolso

Guia farmacia

Toxicidad e interacciones

Consulta farmacia

PRINCIPLES OF SYSTEMIC THERAPY FOR RELAPSE OR STAGE IV DISEASE

FIRST-LINE THERAPY FOR CLEAR CELL HISTOLOGY

Risk	Preferred Regimens	Other Recommended Regimens	Useful in Certain Circumstances
Favorable[a]	• Axitinib + pembrolizumab[b] (category 1) • Cabozantinib + nivolumab[b] (category 1) • Lenvatinib + pembrolizumab[b] (category 1)	• Axitinib + avelumab[b] • Cabozantinib (category 2B) • Ipilimumab + nivolumab[b] • Pazopanib • Sunitinib	• Active surveillance[c] • Axitinib (category 2B) • High-dose IL-2[d] (category 2B)
Poor/ intermediate[a]	• Axitinib + pembrolizumab[b] (category 1) • Cabozantinib + nivolumab[b] (category 1) • Ipilimumab + nivolumab[b] (category 1) • Lenvatinib + pembrolizumab[b] (category 1) • Cabozantinib	• Axitinib + avelumab[b] • Pazopanib • Sunitinib	• Axitinib (category 2B) • High-dose IL-2[d] (category 3) • Temsirolimus[e] (category 3)

SUBSEQUENT THERAPY FOR CLEAR CELL HISTOLOGY

Preferred Regimens	Other Recommended Regimens	Useful in Certain Circumstances
• Cabozantinib (category 1) • Lenvatinib + everolimus • Nivolumab[b] (category 1)	• Axitinib (category 1) • Axitinib + pembrolizumab[b] • Cabozantinib + nivolumab[b] • Ipilimumab + nivolumab[b] • Lenvatinib + pembrolizumab[b] • Pazopanib • Sunitinib • Tivozanib[g] (category 1) • Axitinib + avelumab[b] (category 3)	• Everolimus • Bevacizumab[f] (category 2B) • High-dose IL-2 for selected patients[d] (category 2B) • Sorafenib (category 3) • Temsirolimus[e] (category 2B) • Belzutifan (category 2B)

Table 3. Treatment-Related Adverse Events Occurring in 15% or More of Treated Patients in Either Group.*

Event	Nivolumab plus Ipilimumab (N=547)		Sunitinib (N=535)	
	Any Grade†	Grade 3 or 4	Any Grade‡	Grade 3 or 4
	number of patients (percent)			
All events	509 (93)	250 (46)	521 (97)	335 (63)
Fatigue	202 (37)	23 (4)	264 (49)	49 (9)
Pruritus	154 (28)	3 (<1)	49 (9)	0
Diarrhea	145 (27)	21 (4)	278 (52)	28 (5)
Rash	118 (22)	8 (1)	67 (13)	0
Nausea	109 (20)	8 (1)	202 (38)	6 (1)
Increased lipase level	90 (16)	56 (10)	58 (11)	35 (7)
Hypothyroidism	85 (16)	2 (<1)	134 (25)	1 (<1)
Decreased appetite	75 (14)	7 (1)	133 (25)	5 (<1)
Asthenia	72 (13)	8 (1)	91 (17)	12 (2)
Vomiting	59 (11)	4 (<1)	110 (21)	10 (2)
Anemia	34 (6)	2 (<1)	83 (16)	24 (4)
Dysgeusia	31 (6)	0	179 (33)	1 (<1)
Stomatitis	23 (4)	0	149 (28)	14 (3)
Dyspepsia	15 (3)	0	96 (18)	0
Mucosal inflammation	13 (2)	0	152 (28)	14 (3)
Hypertension	12 (2)	4 (<1)	216 (40)	85 (16)
Palmar–plantar erythrodysesthesia	5 (<1)	0	231 (43)	49 (9)
Thrombocytopenia	2 (<1)	0	95 (18)	25 (5)

RJ Motzer et al. N Engl J Med 2018;378:1277-1290.

Table 3. Adverse Events of Any Cause That Emerged or Worsened during Treatment in at Least 25% of the Patients in Any Treatment Group.*

Event	Lenvatinib plus Pembrolizumab (N=352)		Lenvatinib plus Everolimus (N=355)		Sunitinib (N=340)	
	Any Grade	Grade ≥3†	Any Grade	Grade ≥3†	Any Grade	Grade ≥3†
	number of patients (percent)					
Any event	351 (99.7)	290 (82.4)	354 (99.7)	295 (83.1)	335 (98.5)	244 (71.8)
Diarrhea	216 (61.4)	34 (9.7)	236 (66.5)	41 (11.5)	168 (49.4)	18 (5.3)
Hypertension	195 (55.4)	97 (27.6)	162 (45.6)	80 (22.5)	141 (41.5)	64 (18.8)
Hypothyroidism‡	166 (47.2)	5 (1.4)	95 (26.8)	2 (0.6)	90 (26.5)	0
Decreased appetite	142 (40.3)	14 (4.0)	144 (40.6)	22 (6.2)	105 (30.9)	5 (1.5)
Fatigue	141 (40.1)	15 (4.3)	149 (42.0)	27 (7.6)	125 (36.8)	15 (4.4)
Nausea	126 (35.8)	9 (2.6)	141 (39.7)	9 (2.5)	113 (33.2)	2 (0.6)
Stomatitis	122 (34.7)	6 (1.7)	169 (47.6)	22 (6.2)	131 (38.5)	7 (2.1)
Dysphonia	105 (29.8)	0	84 (23.7)	2 (0.6)	14 (4.1)	0
Weight decrease	105 (29.8)	28 (8.0)	116 (32.7)	26 (7.3)	31 (9.1)	1 (0.3)
Proteinuria	104 (29.5)	27 (7.7)	121 (34.1)	29 (8.2)	43 (12.6)	10 (2.9)
Palmar–plantar erythrodysesthesia syndrome	101 (28.7)	14 (4.0)	81 (22.8)	10 (2.8)	127 (37.4)	13 (3.8)
Arthralgia	99 (28.1)	5 (1.4)	76 (21.4)	5 (1.4)	52 (15.3)	1 (0.3)
Rash	96 (27.3)	13 (3.7)	88 (24.8)	1 (0.3)	47 (13.8)	2 (0.6)
Vomiting	92 (26.1)	12 (3.4)	113 (31.8)	10 (2.8)	68 (20.0)	5 (1.5)
Constipation	89 (25.3)	3 (0.9)	73 (20.6)	1 (0.3)	64 (18.8)	0
Dysgeusia	43 (12.2)	1 (0.3)	59 (16.6)	0	95 (27.9)	1 (0.3)

* Safety assessments were based on as-treated principle and consisted of monitoring and recording all adverse events and serious adverse events with the use of the Common Terminology Criteria for Adverse Events, version 4.03, in the group of patients who received at least one dose of trial drug. Events are listed in descending order of frequency in the lenvatinib-plus-pembrolizumab group. Adverse events were coded to the *Medical Dictionary for Regulatory Activities*, version 21.1 or higher, lower-level term closest to the verbatim term.

R Motzer et al. N Engl J Med 2021;384:1289-1300.

Table 3. Adverse Events of Any Cause That Occurred in 10% or More of Patients in the As-Treated Population.*

Event	Pembrolizumab–Axitinib (N=429)		Sunitinib (N=425)	
	Any Grade	Grade 3, 4, or 5†	Any Grade	Grade 3, 4, or 5‡
	number of patients (percent)			
Diarrhea	233 (54.3)	39 (9.1)	191 (44.9)	20 (4.7)
Hypertension	191 (44.5)	95 (22.1)	193 (45.4)	82 (19.3)
Fatigue	165 (38.5)	12 (2.8)	161 (37.9)	28 (6.6)
Hypothyroidism	152 (35.4)	1 (0.2)	134 (31.5)	1 (0.2)
Decreased appetite	127 (29.6)	12 (2.8)	125 (29.4)	3 (0.7)
Palmar–plantar erythrodysesthesia syndrome	120 (28.0)	22 (5.1)	170 (40.0)	16 (3.8)
Nausea	119 (27.7)	4 (0.9)	134 (31.5)	4 (0.9)
Alanine aminotransferase increased	115 (26.8)	57 (13.3)	64 (15.1)	13 (3.1)
Aspartate aminotransferase increased	112 (26.1)	30 (7.0)	69 (16.2)	10 (2.4)
Dysphonia	109 (25.4)	1 (0.2)	14 (3.3)	0
Cough	91 (21.2)	1 (0.2)	58 (13.6)	2 (0.5)
Constipation	89 (20.7)	0	62 (14.6)	1 (0.2)
Arthralgia	78 (18.2)	4 (0.9)	26 (6.1)	3 (0.7)
Weight decreased	76 (17.7)	13 (3.0)	47 (11.1)	1 (0.2)
Proteinuria	75 (17.5)	12 (2.8)	47 (11.1)	6 (1.4)
Dyspnea	69 (16.1)	7 (1.6)	46 (10.8)	5 (1.2)
Headache	68 (15.9)	4 (0.9)	69 (16.2)	2 (0.5)
Stomatitis	67 (15.6)	3 (0.7)	89 (20.9)	9 (2.1)
Asthenia	65 (15.2)	11 (2.6)	63 (14.8)	13 (3.1)
Pruritus	65 (15.2)	1 (0.2)	25 (5.9)	0
Vomiting	65 (15.2)	1 (0.2)	79 (18.6)	4 (0.9)
Rash	61 (14.2)	1 (0.2)	47 (11.1)	2 (0.5)
Back pain	57 (13.3)	4 (0.9)	43 (10.1)	7 (1.6)
Mucosal inflammation	57 (13.3)	4 (0.9)	93 (21.9)	8 (1.9)
Hyperthyroidism	55 (12.8)	5 (1.2)	16 (3.8)	0
Pyrexia	55 (12.8)	0	43 (10.1)	0
Pain in extremity	51 (11.9)	4 (0.9)	42 (9.9)	4 (0.9)
Abdominal pain	49 (11.4)	5 (1.2)	29 (6.8)	1 (0.2)
Blood creatinine increased	48 (11.2)	2 (0.5)	51 (12.0)	3 (0.7)
Dysgeusia	47 (11.0)	1 (0.2)	131 (30.8)	0
Anemia	34 (7.9)	3 (0.7)	100 (23.5)	21 (4.9)
Dyspepsia	22 (5.1)	0	62 (14.6)	1 (0.2)
Gastroesophageal reflux disease	18 (4.2)	0	48 (11.3)	3 (0.7)
Platelet count decreased	16 (3.7)	1 (0.2)	77 (18.1)	31 (7.3)
Thrombocytopenia	11 (2.6)	0	99 (23.3)	25 (5.9)
Neutropenia	8 (1.9)	1 (0.2)	82 (19.3)	28 (6.6)
Neutrophil count decreased	4 (0.9)	1 (0.2)	50 (11.8)	29 (6.8)
White-cell count decreased	2 (0.5)	0	43 (10.1)	12 (2.8)

Shown are all adverse events that occurred while patients were receiving the assigned treatment or within 30 days after the end of the trial

BI Rini et al. N Engl J Med 2019;380:1116-1127.

Table 3. Adverse Events (As-Treated Population).*

Event	Nivolumab plus Cabozantinib (N=320)		Sunitinib (N=320)
	Any Grade	Grade ≥3	Any Grade
	number of patients (percent)		
Any event	319 (99.7)	241 (75.3)	317 (99.1)
Diarrhea	204 (63.8)	22 (6.9)	151 (47.2)
Palmar–plantar erythrodysesthesia	128 (40.0)	24 (7.5)	130 (40.6)
Hypertension	111 (34.7)	40 (12.5)	119 (37.2)
Hypothyroidism	109 (34.1)	1 (0.3)	94 (29.4)
Fatigue	103 (32.2)	11 (3.4)	111 (34.7)
Increased ALT level	90 (28.1)	17 (5.3)	27 (8.4)
Decreased appetite	90 (28.1)	6 (1.9)	65 (20.3)
Nausea	85 (26.6)	2 (0.6)	98 (30.6)
Increased AST level	81 (25.3)	11 (3.4)	35 (10.9)
Dysgeusia	76 (23.8)	0	69 (21.6)
Asthenia	71 (22.2)	14 (4.4)	59 (18.4)
Rash	69 (21.6)	6 (1.9)	26 (8.1)
Mucosal inflammation	66 (20.6)	3 (0.9)	81 (25.3)
Pruritus	60 (18.8)	1 (0.3)	14 (4.4)
Arthralgia	59 (18.4)	1 (0.3)	29 (9.1)
Back pain	58 (18.1)	5 (1.6)	40 (12.5)
Vomiting	55 (17.2)	6 (1.9)	66 (20.6)
Cough	55 (17.2)	0	51 (15.9)
Dysphonia	55 (17.2)	1 (0.3)	11 (3.4)
Stomatitis	54 (16.9)	8 (2.5)	79 (24.7)
Increased lipase level	53 (16.6)	20 (6.2)	38 (11.9)
Hyponatremia	51 (15.9)	30 (9.4)	28 (8.8)
Abdominal pain	50 (15.6)	5 (1.6)	27 (8.4)
Headache	50 (15.6)	0	37 (11.6)
Anemia	48 (15.0)	6 (1.9)	81 (25.3)
Increased amylase level	47 (14.7)	10 (3.1)	29 (9.1)
Hypophosphatemia	46 (14.4)	19 (5.9)	18 (5.6)
Hypomagnesemia	44 (13.8)	2 (0.6)	15 (4.7)
Increased blood creatinine level	42 (13.1)	4 (1.2)	43 (13.4)
Constipation	39 (12.2)	3 (0.9)	40 (12.5)
Pyrexia	39 (12.2)	2 (0.6)	27 (8.4)
Muscle spasms	38 (11.9)	0	5 (1.6)
Increased blood alkaline phosphatase level	37 (11.6)	3 (0.9)	26 (8.1)
Upper respiratory tract infection	36 (11.2)	1 (0.3)	12 (3.8)
Decreased weight	35 (10.9)	2 (0.6)	10 (3.1)
Peripheral edema	34 (10.6)	1 (0.3)	28 (8.8)
Proteinuria	33 (10.3)	9 (2.8)	25 (7.8)
Dizziness	33 (10.3)	1 (0.3)	19 (5.9)
Hyperthyroidism	32 (10.0)	2 (0.6)	9 (2.8)
Dyspepsia	26 (8.1)	0	39 (12.2)
Thrombocytopenia	25 (7.8)	2 (0.6)	62 (19.4)
Gastroesophageal reflux disease	25 (7.8)	0	36 (11.2)
Epistaxis	22 (6.9)	0	32 (10.0)
Decreased platelet count	18 (5.6)	0	61 (19.1)
Neutropenia	15 (4.7)	2 (0.6)	50 (15.6)

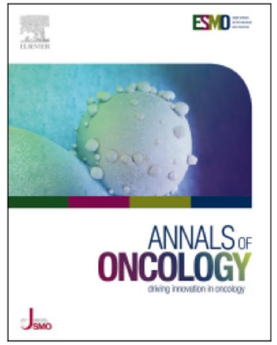
* Shown are adverse events of any cause that occurred in at least 10% of patients in either group while pati

TK Choueiri et al. N Engl J Med 2021;384:829-841.

Puntos de control

.Toxicidad

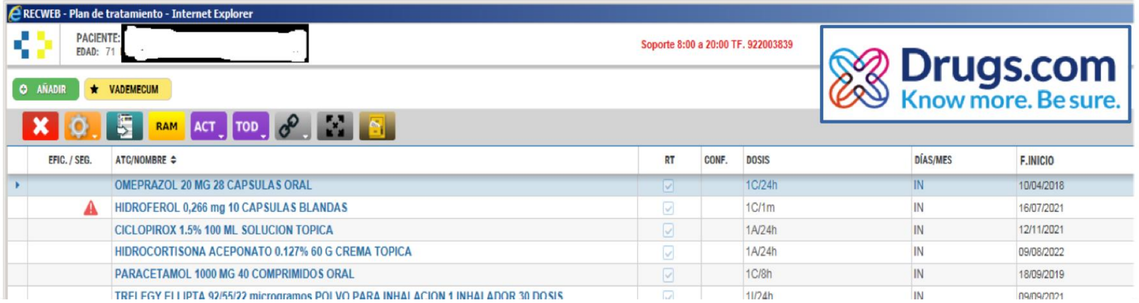
- H.Tiroideas cada ciclo hasta 4º
- Enzimas Hepaticos cada ciclo
- Hemograma cada ciclo
- Proteinuria



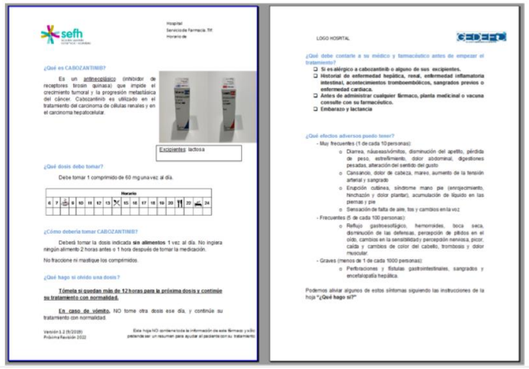
Haanen J, Obeid M, Spain L, Carbonnel F, Wang Y, Robert C, Lyon AR, WickW, Kostine M, Peters S, Jordan K, Larkin J, on behalf of the ESMO Guidelines Committee, Managementof toxicities from immunotherapy: ESMO Clinical Practice Guideline for diagnosis, treatment and followup, Annals of Oncology (2022), doi: https://doi.org/10.1016/j.annonc.2022.10.001.

.Interacciones: ++ o – CYP3A4/5

- Antibioticos, antifungicos,antivirales
- Antiepilepticos
- Diltiazem y prolongadores del QT



CONSULTA DE FARMACIA



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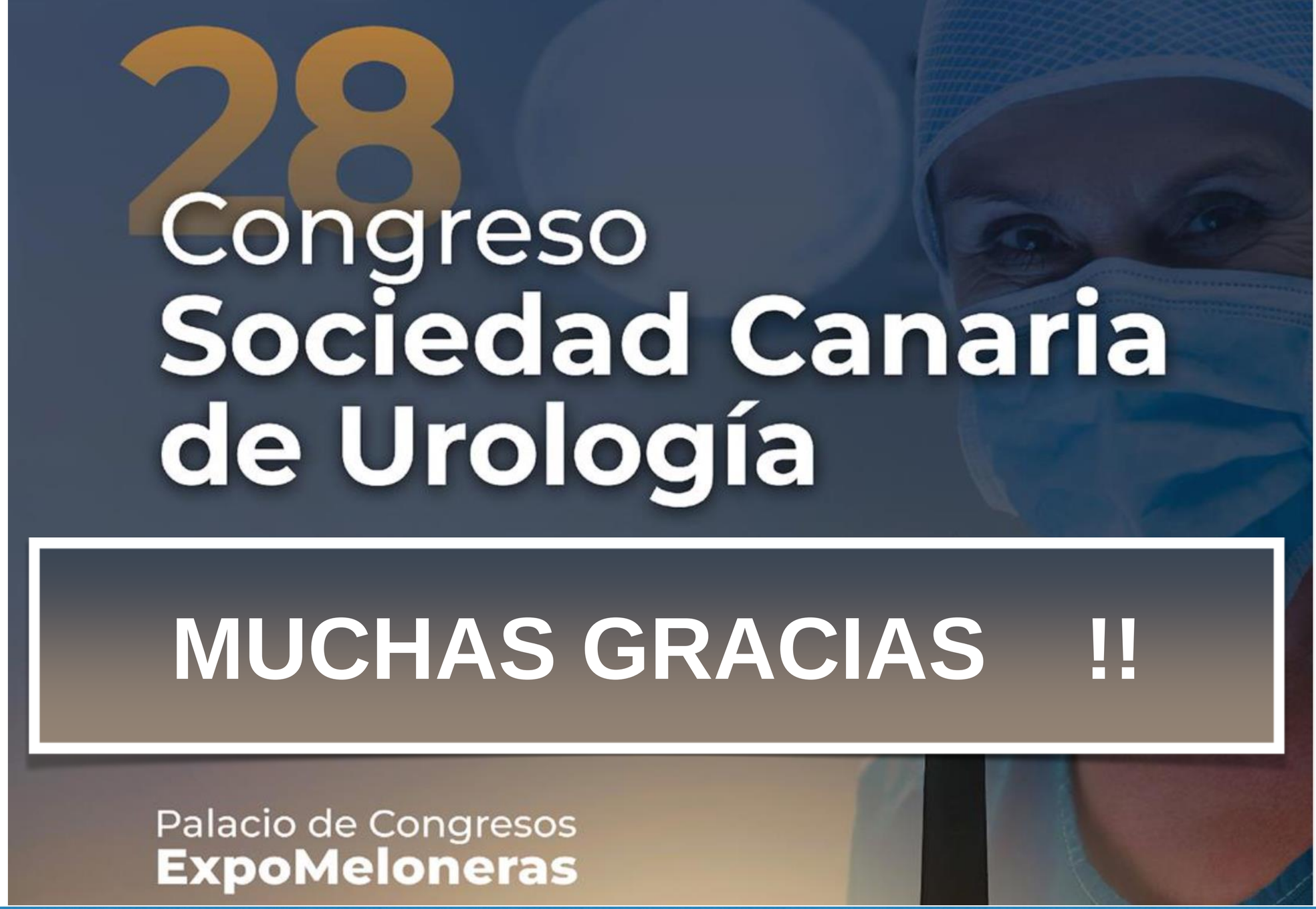
HOJAS DE INFORMACIÓN


28
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MUCHAS GRACIAS !!
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