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Título de la presentación

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CLINICAL GUIDES IN ONCOLOGY

SEOM SOGUG clinical guideline for treatment of kidney cancer (2022)

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ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

ANNALS OF ONCOLOGY driving innovation in oncology

SPECIAL ARTICLE

ESMO Clinical Practice Guideline update on the use of immunotherapy in early stage and advanced renal cell carcinoma

T. Powles[1], L. Albiges[2], A. Bex[3,4], V. Grünwald[5], C. Porta[6,7], G. Procopio[8], M. Schmidinger[9], C. Suárez[10] & G. de Velasco[11], on behalf of the ESMO Guidelines Committee*

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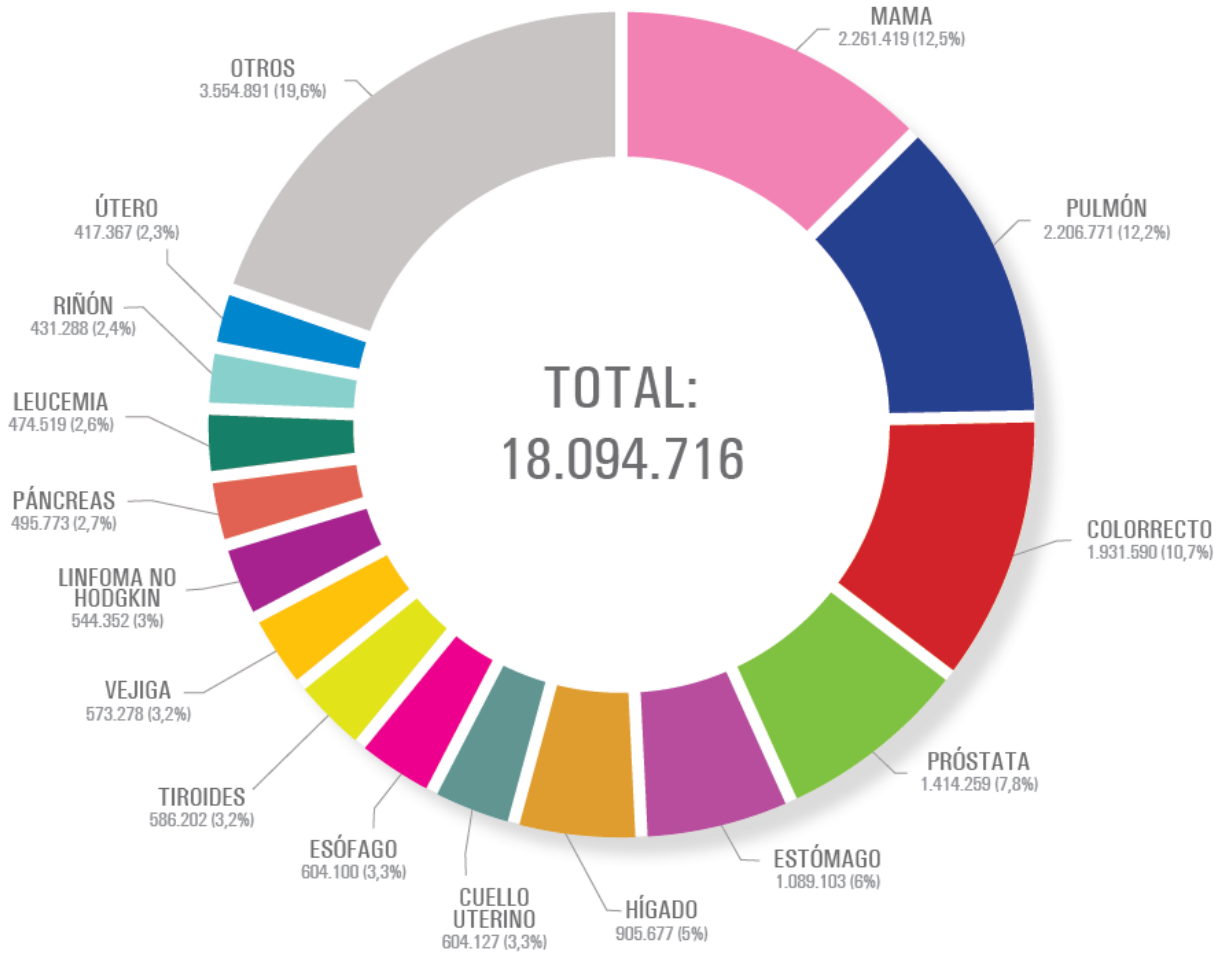
Available online 28 September 2021

Incidencia Cáncer Mundo

Figura 2. Tumores más frecuentemente diagnosticados en el mundo. Estimación para el año 2020, ambos sexos (excluidos tumores cutáneos no melanoma).



EPIDEMIOLOGY

-Renal cell carcinoma (RCC) constitutes 80% of all primary renal neoplasms.

-The incidence remains stable in recent years with 431,288 new cases and 179,368 deaths in 2020 according to data published by GLOBOCAN.

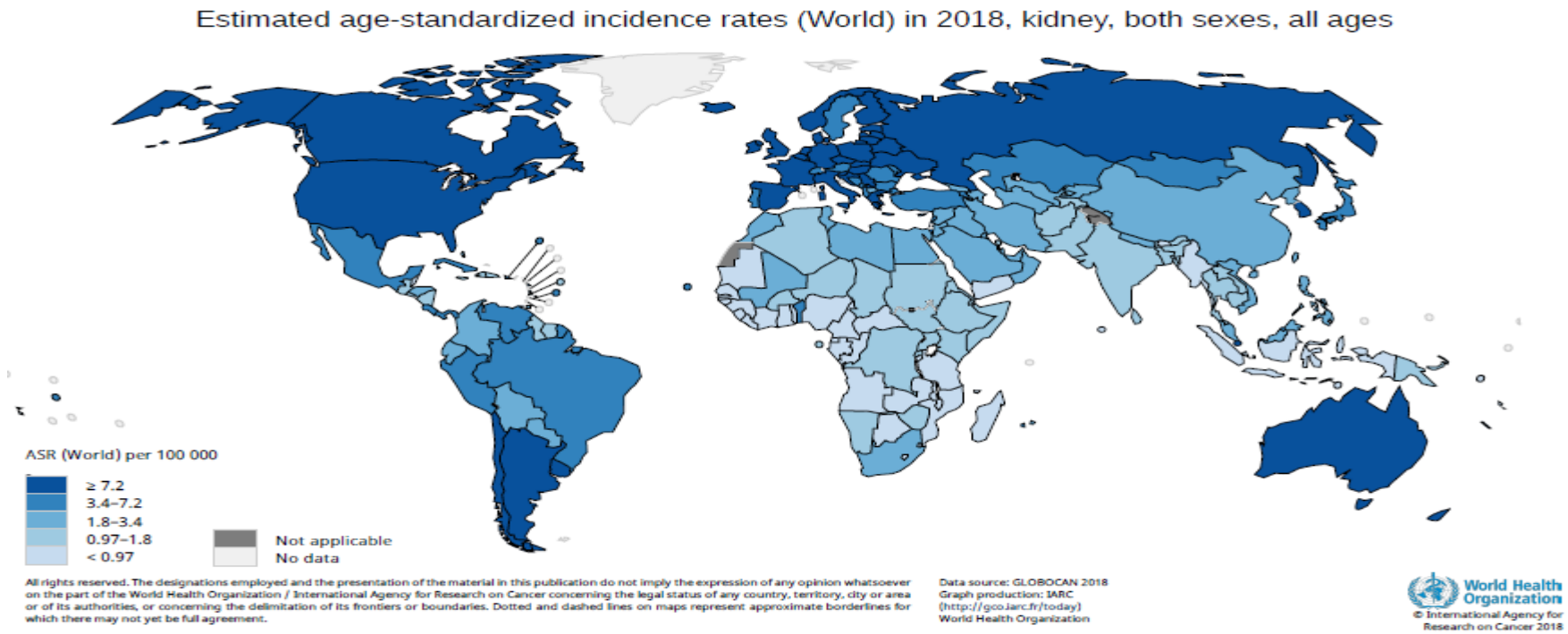
-In Spain, the estimated incidence in 2022 was 8078 new cases (5572 in men and 2506 in women).

-It is twice as common in males and the median age at diagnosis is 64 years.

Epidemiología

- Incremento en el diagnóstico de la enfermedad localizada y descenso de la metastásica
- En el 20% de pacientes tratados con enfermedad localizada, el tumor recidiva.
- Aprox. 20% de pacientes son diagnosticados con enfermedad metastásica.

Epidemiología Cáncer renal



FACTORES DE RIESGO

FACTORES DE RIESGO

• Máxima incidencia 60 – 70 años

• **Tabaquismo**: - Dosis-dependiente (reducción del riesgo tras 10 años de abstención)
• **HTA**
• **Obesidad**

• **Enfermedad renal quística adquirida**: - Mayor riesgo en pacientes sometidos a hemodiálisis durante más de 3 años

• **Enfermedad hereditaria**: - 95% son esporádicos - 5% pertenecen a un síndrome hereditario - x2-3 veces si existe un familiar de primer grado afectado

Clasificacion A.P. de la OMS 2022

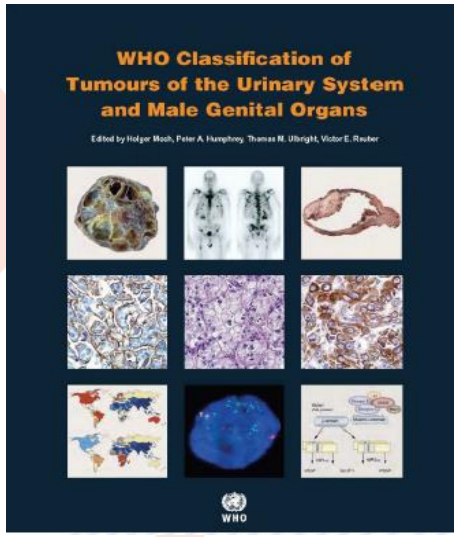
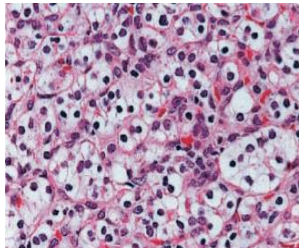


Table 3 WHO 2022 Classification of renal cell tumors

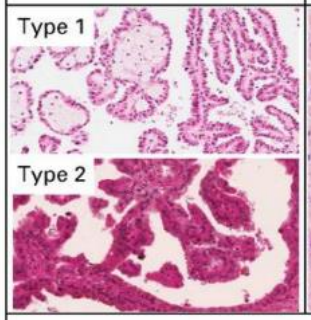
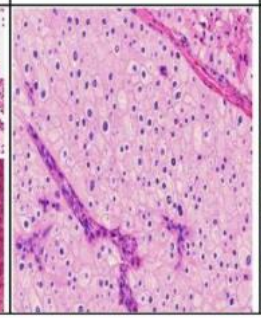
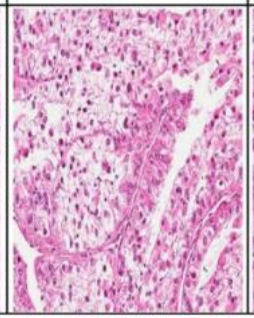
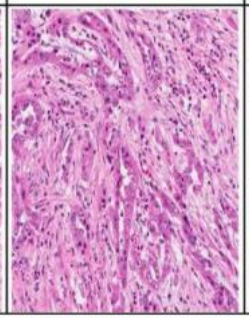
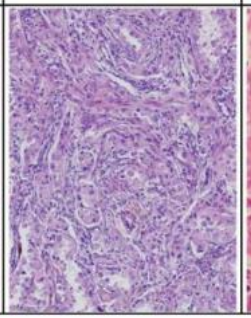
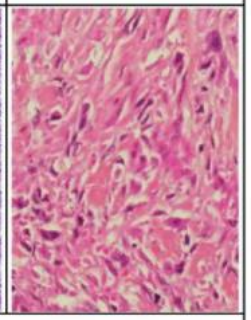
Clear cell renal tumors
Clear cell renal cell carcinoma
Multilocular cystic renal neoplasm of low malignant potential
Papillary renal tumors
Papillary adenoma
Papillary renal cell carcinoma
Oncocytic and chromophobe renal tumors
Oncocytoma
Chromophobe renal cell carcinoma
Other oncocytic tumors of the kidney
Collecting duct tumors
Collecting duct carcinoma
Other renal tumors
Clear cell papillary renal cell tumor
Mucinous tubular and spindle cell carcinoma
Tubulocystic renal cell carcinoma
Acquired cystic disease-associated renal cell carcinoma
Eosinophilic solid and cystic RCC
Renal cell carcinoma, NOS
Molecularly defined renal carcinoma
TFE3-rearranged renal cell carcinoma
TFEB-altered renal cell carcinoma
ELOC (formerly *TCEB1*-) mutated renal cell carcinoma
Fumarate hydratase-deficient renal cell carcinoma
Hereditary leiomyomatosis and renal cell carcinoma syndrome-associated renal cell carcinoma
Succinate dehydrogenase-deficient renal cell carcinoma
ALK rearrenged renal cell carcinoma
Medullary carcinoma, NOS
SMARCB1-deficient medullary-like renal cell carcinoma
SMARCB1-deficient undifferentiated renal cell carcinoma, NOS
SMARCB1-deficient undifferentiated renal cell carcinoma of other specific subtypes

Tipo A.P. más frecuente



Tipo	Céls claras
Asociadas Mutaciones	VHL
Incidencia (%)	75
Locus	3p25

Menos frecuentes

Papillary		Chromophobe	Translocation	Collecting Duct	Medullary	Sarcomatoid
						
Cytogenetic Alterations						
Type 1 Gain Chr. 7, 17	**Type 2** Del Chr. 9p	Del Chr. 1, 2, 6, 10, 13, 17	Transloc. Xp11.2 [*TFE3*] Transloc. (6;11) [*TFEB*]	Del Chr. 8p, 16p, 1p, 9p Gain Chr. 13q	Del. 22q	-
Molecular Alterations						
Type 1 *MET* *TERT* *CDKN2A/B* *EGFR*	**Type 2** *SETD2* *CDKN2A/B* *NF2* *FH* *TERT*	*TP53* *PTEN* *TERT* fusion *MTOR, TSC1/2* *MT-ND5*	*TFE3* fusion *TFEB* fusion	*NF2* *SETD2* *SMARCB1* *CDKN2A*	*SMARCB1* rearrangements	*TP53* *CDKN2A* *NF2* *RELN* *BAP1* *ARID1A*
Pathway Deregulations						
Activation Cell cycle MAP kinases **Deregulation** Chromatin remodeling	**Activation** Cell cycle Hippo NRF2-ARE **Deregulation** Chromatin remodeling Metabolism Methylation	**Activation** MTOR APOBEC **Deregulation** Metabolism	**Activation** TNF TGF-β MTOR **Downregulation** HIF/VEGF **Deregulation** Chromatin remodeling	**Activation** Immune response Cell cycle **Deregulation** Metabolism	-	**Activation** Cell cycle TGF-β **Deregulation** Chromatin remodeling

Albiges L et al. J Clin Oncol 2018

[1]Modified from Linehan WM et al. *J Urol*. 2003;170:2163-2172. [2]Kim WY. *J Clin Oncol*. 2004;22:4991-5004.

Changes in new classification

Changes in nomenclature from

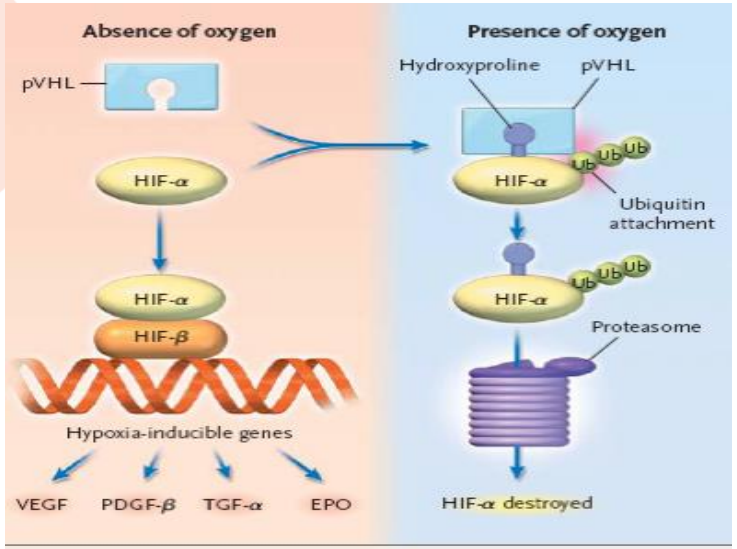
- "clear cell papillary renal cell carcinoma (RCC)" to "clear cell renal cell tumor"
- "TCEB1-mutated RCC" to "ELOC-mutated RCC"
- "hereditary leiomyomatosis and renal cell carcinoma" to "fumarate hydratasedeficient RCC"
- "RCC-unclassified" to "RCC-NOS".

Type 1/2 papillary RCC subcategorization has been eliminated.

A category of "**other oncocytic tumors,"** including LOT, eosinophilic vacuolated tumor, and hybrid oncocytic tumor, has been introduced.

Eosinophilic solid and cystic RCC is accepted as a new and independent tumor entity.

PATOGENIA



Control of Hypoxia-Inducible Factor (HIF) by the Gene Product of the von Hippel–Lindau Gene (pVHL).

HIF is a heterodimer consisting of an α subunit and a β subunit. In the presence of oxygen, HIF-α is hydroxylated on one of two proline residues. The pVHL binds to hydroxylated HIF-α and directs the attachment of a polyubiquitin chain, which targets HIF-α for destruction by a multiprotein complex called the proteasome. Under hypoxic conditions, or in the absence of pVHL, HIF-α accumulates and activates the transcription of hypoxia-inducible genes. VEGF denotes vascular endothelial growth factor, PDGF-β platelet-derived growth factor β, TGF-α transforming growth factor α, and EPO erythropoietin.

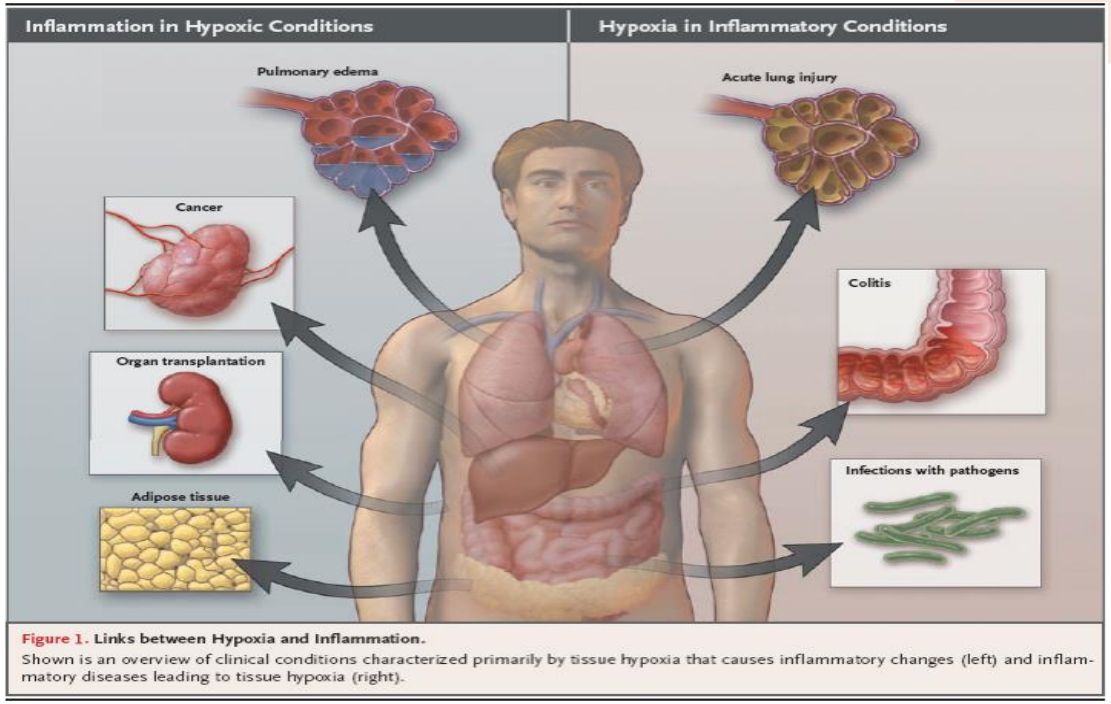


Figure 1. Links between Hypoxia and Inflammation.

Shown is an overview of clinical conditions characterized primarily by tissue hypoxia that causes inflammatory changes (left) and inflammatory diseases leading to tissue hypoxia (right).

Motzer R. NEJM 353;23 2005

Patogenia del Carcinoma Renal

Existen dos formas distintas:

Esporádico: 90-95%

Síndrome hereditarios: 5- 10%

Inactivación del gen supresor tumoral VHL.

Es la alteración genética más frecuentemente presente.

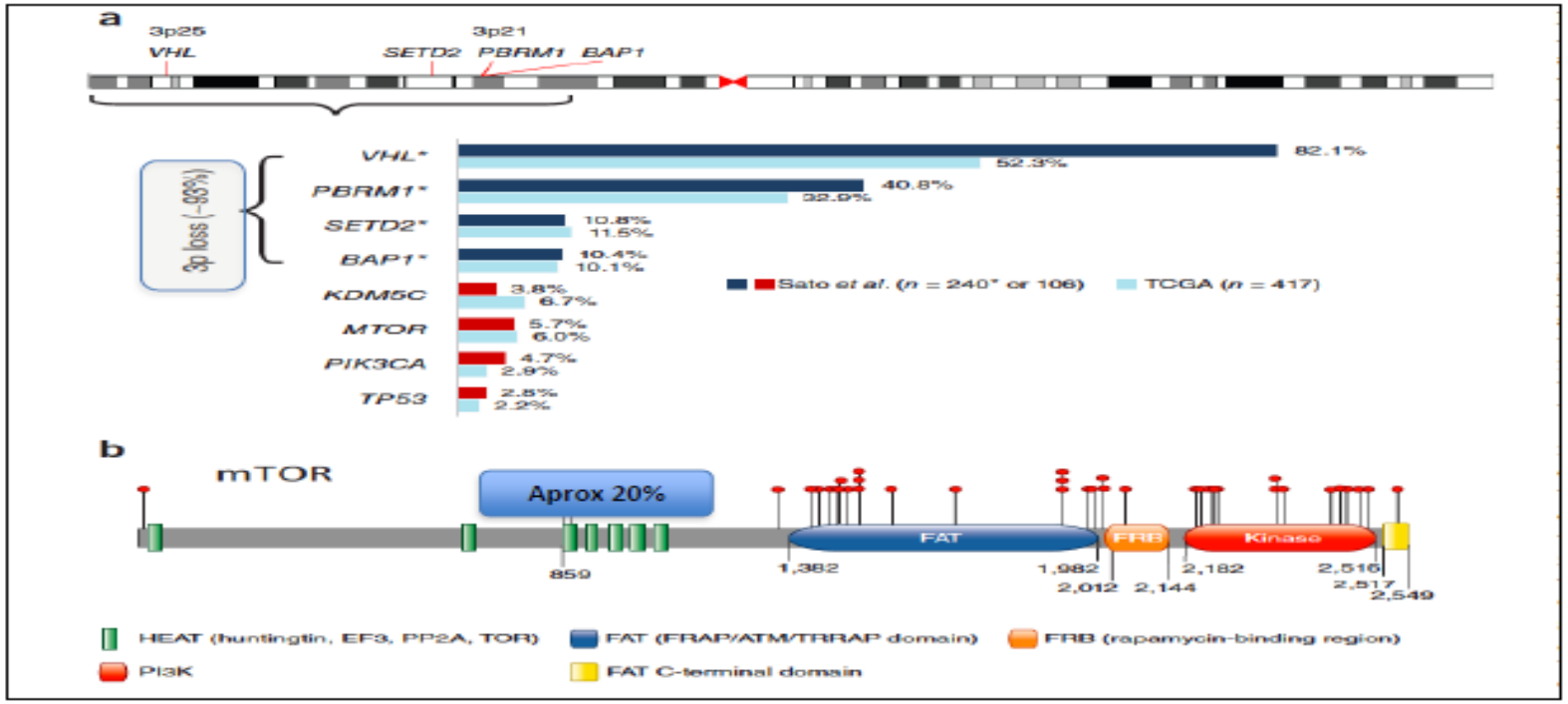
Cáncer Renal Hereditario:

- Carcinoma renal en la enfermedad de Von Hippel-Lindau
  - Gen VHL.
- Carcinoma renal papilar hereditario (CRPH).
  - Gen Met. Papilar (antes tipo I)
- Leiomiomatosis Hereditaria Cáncer renal (LHCR).
  - Gen FH. Papilar (antes tipo II)
- Birtt-Hogg-Dubé.
  - Gen BHD. Carcinoma cromófobo, oncocitoma.
- Complejo de la Esclerosis Tuberosa.
  - Gen TSC
- Traslocación del cromosoma 3

ARTICLE OPEN

Comprehensive molecular characterization of clear cell renal cell carcinoma

The Cancer Genome Atlas Research Network*



4 JULY 2013 | VOL 499 | NATURE

DIAGNÓSTICO

Presentación Clínica

Presentación clínica

- Suele estar clínicamente oculto.
- Considerado el tumor del internista por la posibilidad de Sd. Paraneoplásicos asociados.
- La presentación clásica es:

1. Dolor.
2. Hematuria.
3. Masa.

PRUEBAS DIAGNÓSTICAS

Recommendations

- CT scan is the gold standard for RCC staging. Level of evidence: III. Grade of recommendation: A.
- Abdominal MRI is an alternative in various circumstances. Level of evidence: III. Grade of recommendation: C.
- Neither bone scans nor brain CT (nor MRI) are recommended for routine clinical practice. Level of evidence: III. Grade of recommendation: D.
- In patients without previous tumor diagnosis, a renal tumor core biopsy is recommended before treatment with ablative therapies, as well as in cases of metastatic disease, prior to starting systemic treatment. Level of evidence: III. Grade of recommendation: A.

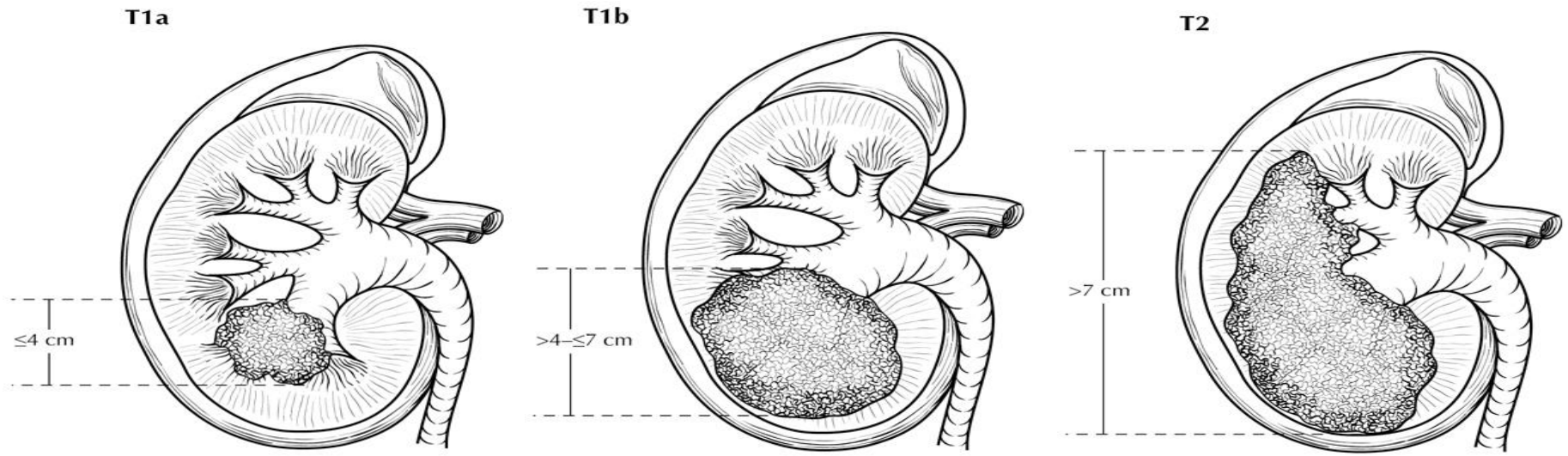
Mendez MJ et al, Clinical and Translational Oncology (2023) 25:2732–2748

Estadios del Carcinoma Renal

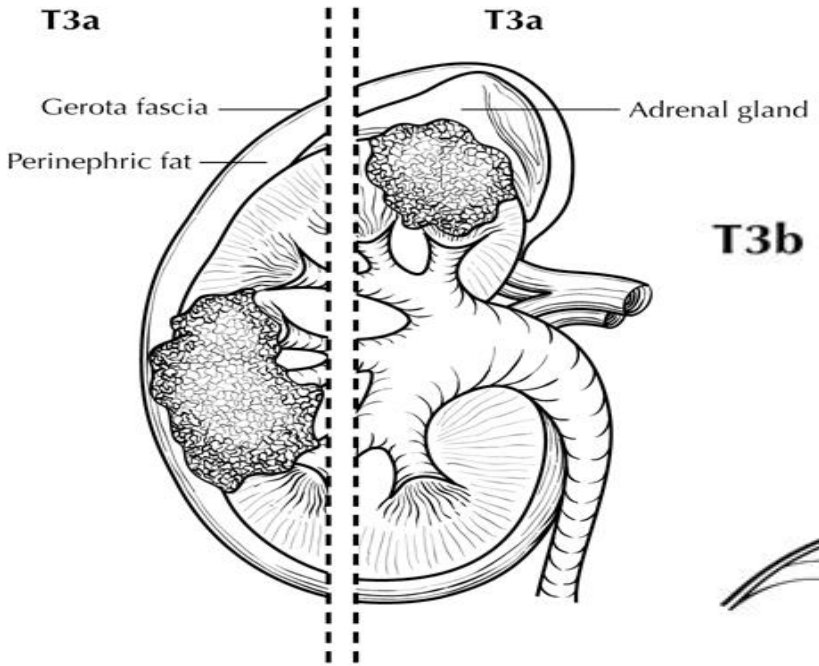
Table 1 Kidney cancer TNM-staging AJCC UICC 2017

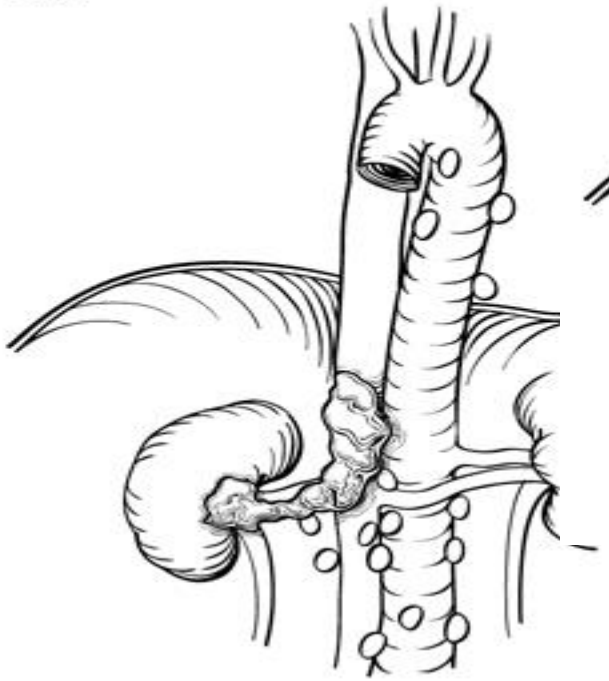
Stage	Definition	Subdivision
Tumour stage		
Tx	Primary tumour cannot be assessed	
T0	No evidence of primary tumour	
T1	Tumour 7 cm or less in greatest dimension, limited to the kidney	**T1a:** ≤ 4 cm **T1b:** > 4 cm but < 7 cm
T2	Tumour more than 7 cm in greatest dimension, limited to the kidney	**T2a:** > 7 cm but < 10 cm **T2b:** > 10 cm
T3	Tumour extends into major veins or perinephric tissues but not into the ipsilateral adrenal gland and not beyond Gerota fascia	**T3a:** Tumour extends into the renal vein or its segmental branches, or tumour invades the pelvicalyceal system or tumour invades perirenal and/or renal sinus fat (peripelvic) fat but not beyond Gerota fascia **T3b**: Tumour extends into vena cava below diaphragm **T3c:** Tumour extends into vena cava above the diaphragm or invades the wall of the vena cava
T4	Tumour invades beyond Gerota fascia (including contiguous extension into the ipsilateral adrenal gland)	
Regional lymph nodes		
Nx	Regional lymph nodes cannot be assessed	
N0	No regional lymph node metastasis	
N1	Metastasis in regional lymph node(s)	
Distant metastasis		
M0	No distant metastasis	
M1	Distant metastasis	

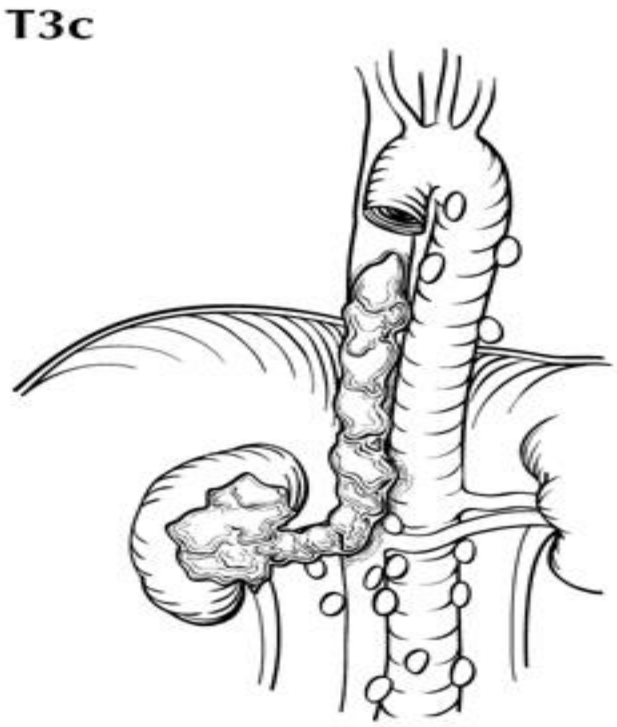
TNM



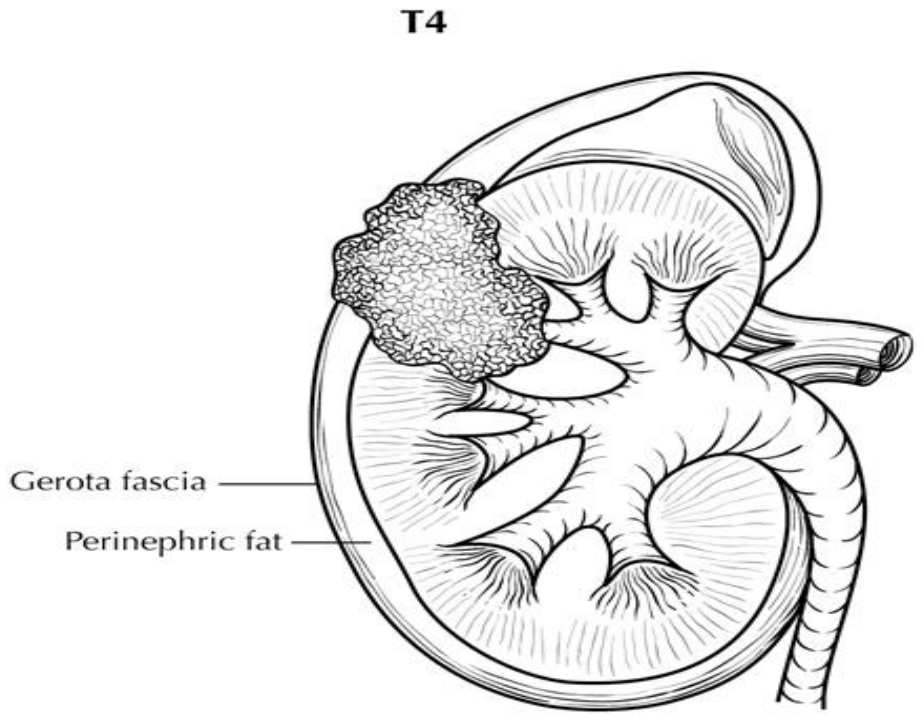
TNM


T3a
T3a
Gerota fascia
Perinephric fat
Adrenal gland


T3b


T3c

TNM



Estadios del Carcinoma Renal

Table 2 Stage grouping for RCC based on AJCC TNM 2017

Stage			
Stage I	T1	N0	M0
Stage II	T2	N0	M0
Stage III	T3	N0	M0
	T1, T2, T3	N1	M0
Stage IV	T4	Any N	M0
	Any T	Any N	M1

TRATAMIENTO DEL CÁNCER RENAL LOCALIZADO

Recommendations

- Partial nephrectomy is recommended in T1 tumors, as well as in bilateral tumors or in patients with only one functioning kidney. Level of evidence: I. Grade of recommendation A.
- Radical nephrectomy is recommended in T2-4 tumors. Level of evidence: II. Grade of recommendation: A.
- Treatment with adjuvant pembrolizumab is an option for intermediate- or high-risk patients, as well as after complete resection of oligometastatic disease. More data are required in the future, including positive overall survival data. Level of evidence: I. Grade of recommendation: C.
- Surgical intervention should be contemplated when feasible, as it may be associated with prolonged survival. Level of evidence: III.

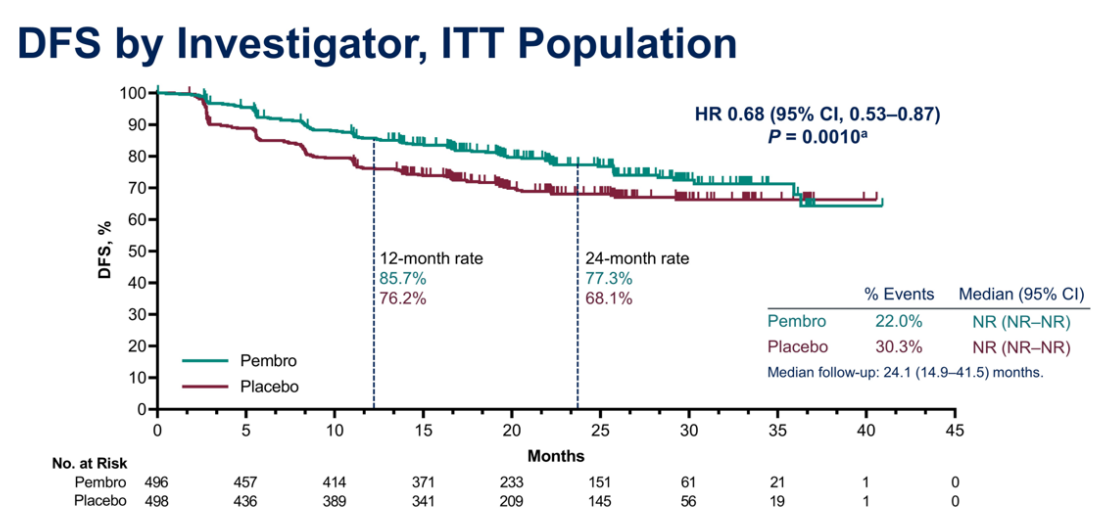
In ***tumors smaller than 7 cm*** (T1) the recommended treatment is partial nephrectomy (via open, laparoscopic or robot-assisted laparoscopic approaches), a technique that enables similar results to be achieved with better preservation of renal function [32]. Radical nephrectomy is an alternative if partial nephrectomy is not possible. Ablative procedures are options for elderly patients or those with high surgical risk, and in cases of multiple bilateral tumors, such as hereditary RCC, especially in small tumors. Renal biopsy is recommended if surgery is not possible [33]. Active surveillance is an option in elderly patients with significant comorbidities or short life expectancy and solid tumors < 4 cm [34].

In ***T2 tumors measuring > 7 cm,*** laparoscopic radical nephrectomy is the treatment of choice, while open surgery is called for in ***T3 and T4 tumors***, albeit laparoscopic surgery can be contemplated in certain situations. Lymphadenectomy and suprarenalectomy are not indicated if there is no evidence of invasion on imaging tests(1), although the latter should be considered in upper pole tumors > 4 cm or > T3 [35].

The evidence regarding the treatment of venous thrombus is based on retrospective studies and poses a challenge not exempt of complications. Surgical intervention should be evaluated when feasible, as it may be associated with prolonged survival [36].

ADYUVANCIA CON PEMBROLIZUMAB

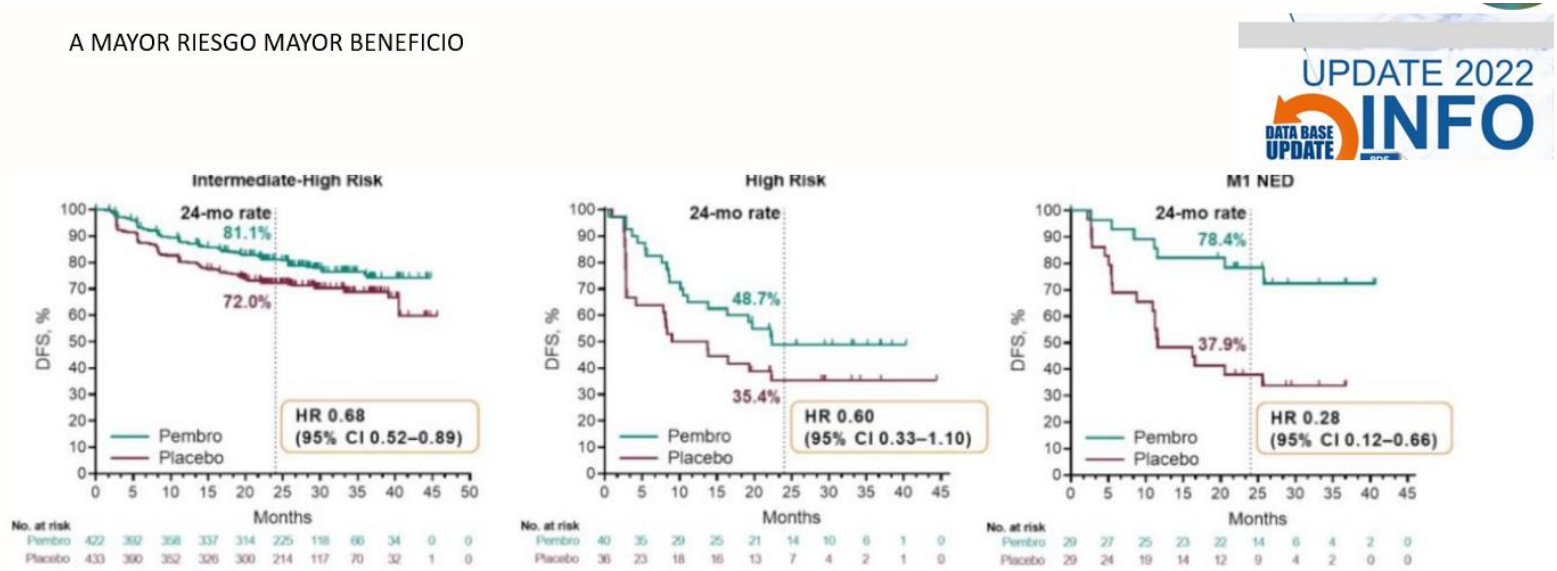
Intermediate-High Risk		High Risk		M1 NED
pT2	pT3	pT4	Any pT	NED after resection of oligometastatic sites ≤1 year from nephrectomy
Grade 4 or sarcomatoid	Any grade	Any grade	Any grade	
N0	N0	N0	N+	
M0	M0	M0	M0	



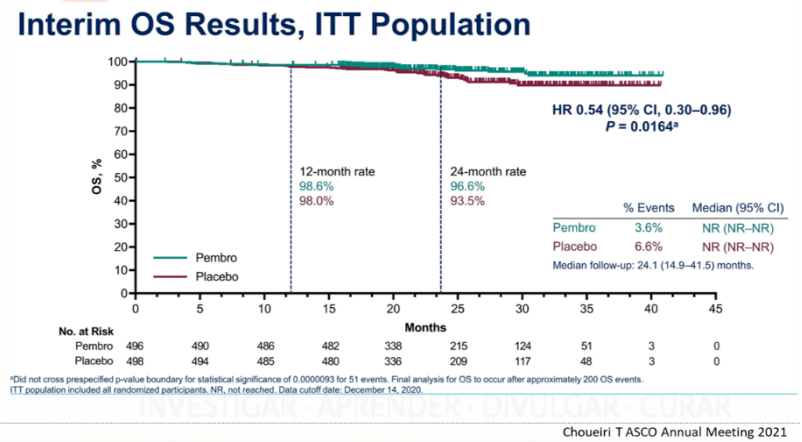
Choueiri T ASCO Annual Meeting 2021

ADYUVANCIA CON PEMBROLIZUMAB

A MAYOR RIESGO MAYOR BENEFICIO



Choueiri ASCO GU 2022. Results from 30-month follow-up of KEYNOTE-564



Choueiri T ASCO Annual Meeting 2021

ASCO GU 2024
Overall survival results from the phase III KEYNOTE-564 trial examining adjuvant pembrolizumab for the treatment of clear cell renal cell carcinoma. (Abstract LBA359)

NINGUN OTRO FÁRMACO DA BENEFICIO EN ADYUVANCIA SALVO SUTENT EN DFS (S TRAC)

MANEJO CÁNCER RENAL METASTÁSICO

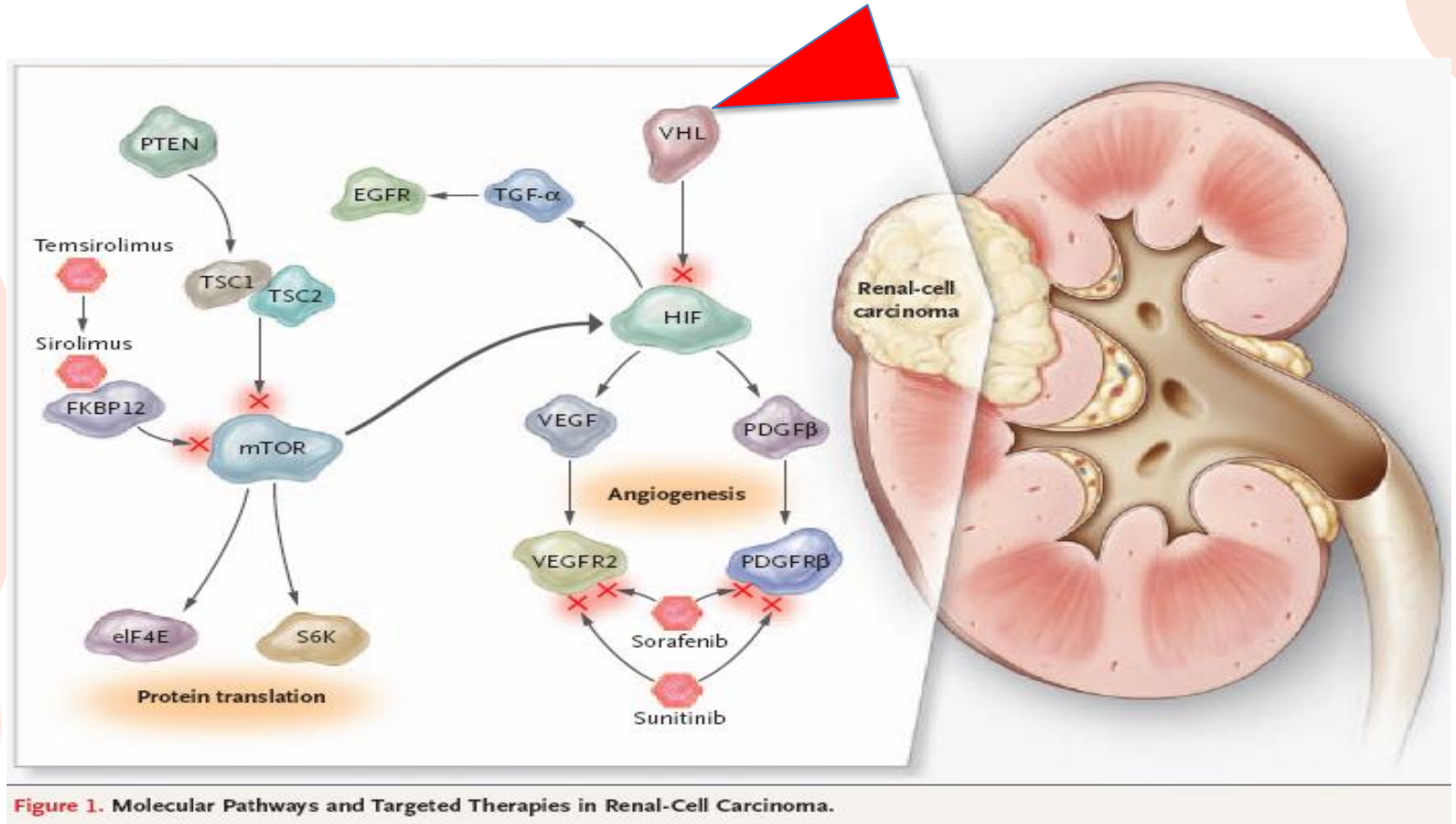


Figure 1. Molecular Pathways and Targeted Therapies in Renal-Cell Carcinoma.

n engl j med 356;2 www.nejm.org january 11, 2007

Factores de riesgo para RCC avanzado:

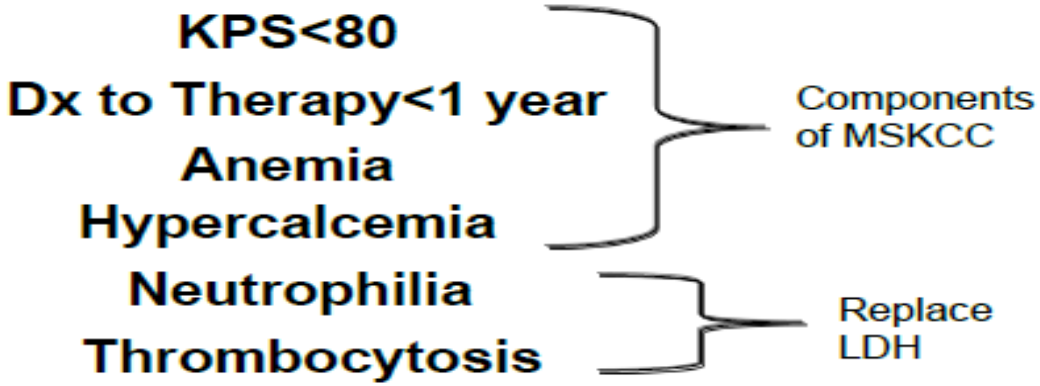
Memorial Sloan Kettering Cancer Center (MSKCC) y
Cleveland Clinic Foundation (CCF)

Factores pronósticos	MSKCC Criteria[1,2]	CCF Criteria[2]
Indíce de Karnofsky	**< 80**	**-**
Tiempo de la nefrectomía hasta M1	**< 12 meses**	< 12 meses
Hemoglobina	**< límite inferior normal**	<Límite inferior normal
Lactato deshidrogenasa	**> 1.5 x límite superior normal**	> 1.5 x límite superior normal
Calcio sérico corregido	**> 10.0 mg/dL**	> 10.0 mg/dL
Radioterapia previa	**-**	si
Presencia de metástasis hepáticas, pulmonares, o retroperitoneales	**-**	si

[1] Motzer RJ, et al. *J Clin Oncol*. 2002;20:289-296.
[2] Mekhail TM, et al. *J Clin Oncol.* 2005;23:832-841.

CRITERIOS DE HENG

NEW MODEL FOR VEGF-TARGETED THERAPY



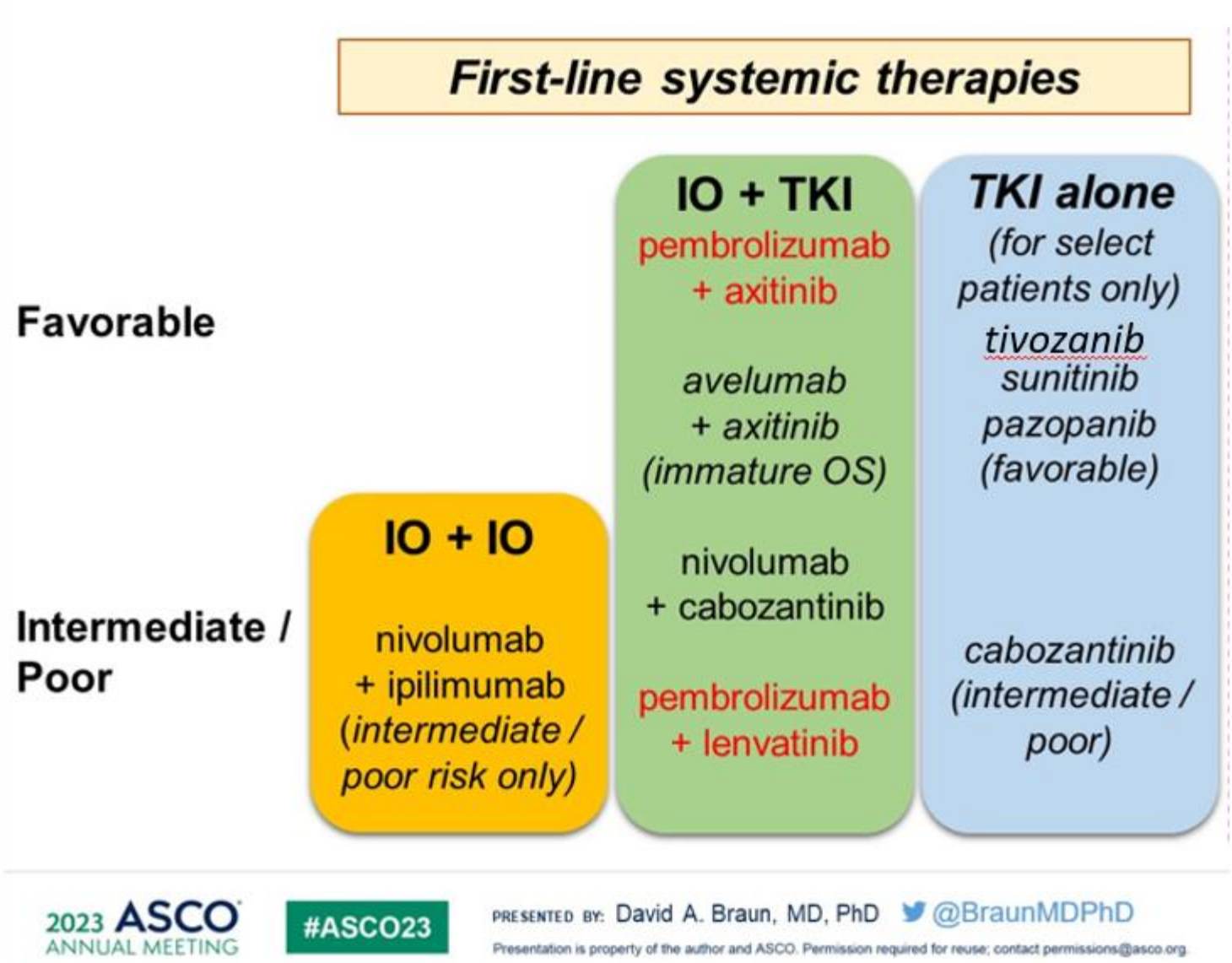
International mRCC Consortium, JCO 2009

MANEJO CÁNCER RENAL METASTÁSICO

Recommendations

- Debulking or cytoreductive nephrectomy should not be deemed mandatory in patients with intermediate-poor IMDC/MSKCC risk who require systemic therapy. Level of evidence: I. Grade of recommendation: A.
- Cytoreductive nephrectomy may play a role in the management of advanced renal cell carcinoma in individuals with limited metastatic burden amenable to surveillance or metastasectomy, in patients requiring palliation, and potentially delayed cytoreductive nephrectomy in patients with a favorable response or stable disease after initial systemic therapy. Level of Evidence: II. Grade of recommendation: B.
- Metastasectomy can be contemplated in selected patients having a limited number of metastases or long metachronous disease-free interval. Level of evidence: II. Grade or recommendation: C.

PRIMERA LÍNEA CÁNCER RENAL METASTÁSICO



PRIMERA LÍNEA CÁNCER RENAL METASTÁSICO

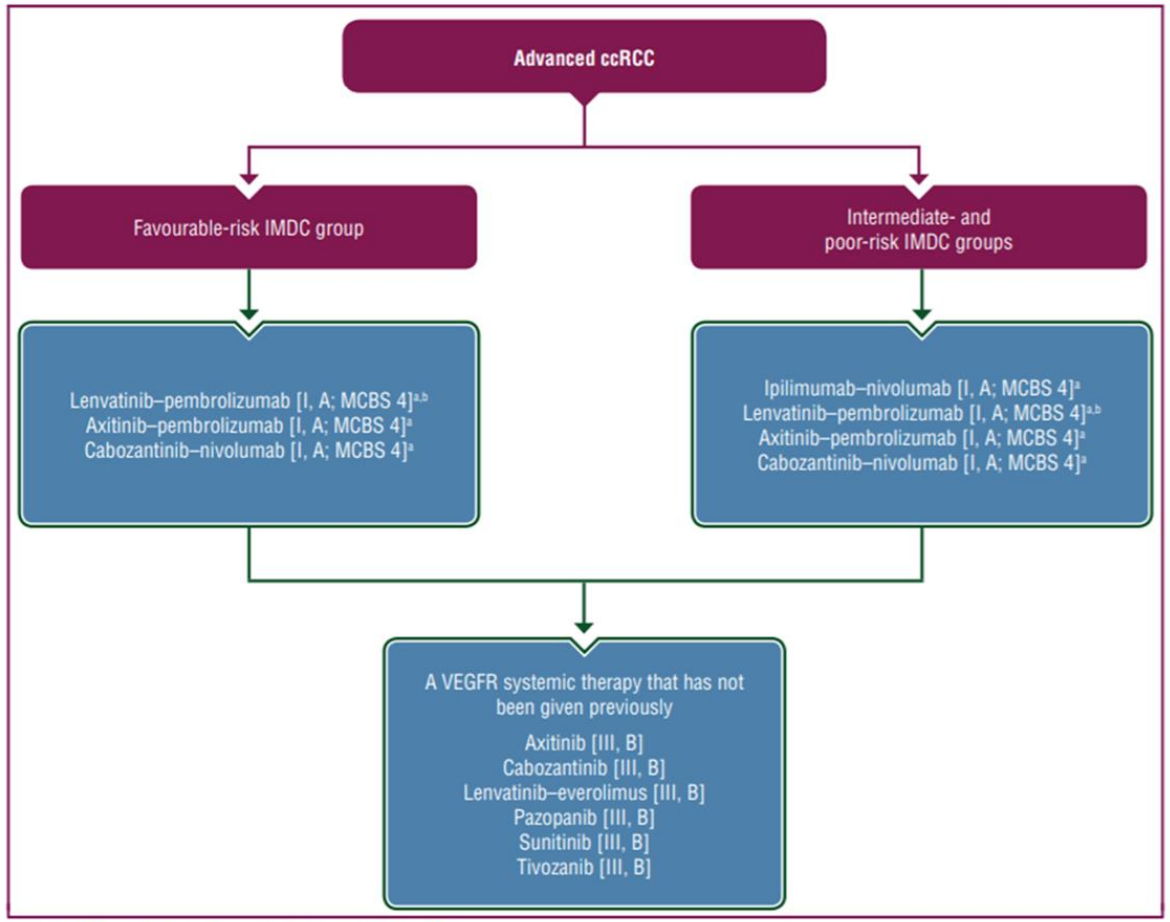


Figure 1. Systemic first- and second-line treatment of ccRCC.

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Recommendations

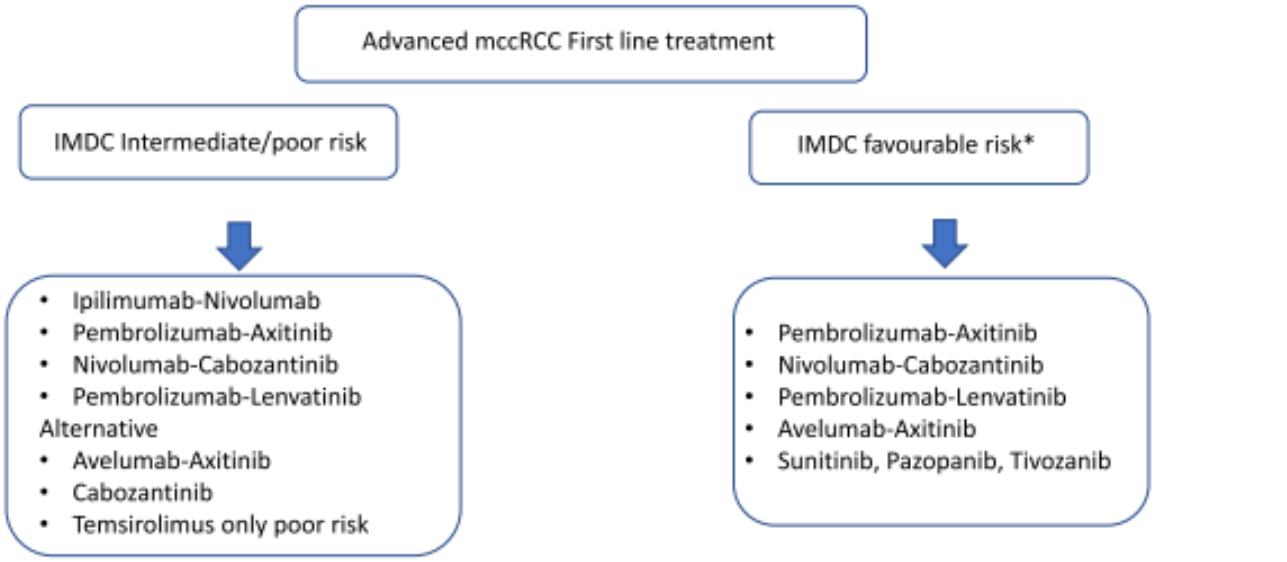
Until predictive factors became reliable, the choice of first-line treatment for patients with metastatic ccRCC should be based on the local availability of approved drugs, patient comorbidities and prognosis, including the need for a quick response, as well as the design of a global therapeutic strategy with salvage options for subjects who do not respond or who relapse (Fig. 1).

Considering the whole population of patients with metastatic ccRCC:

- The combination of pembrolizumab + axitinib, nivolumab + cabozantinib, or pembrolizumab + lenvatinib can be considered the first options based on the benefit obtained in OS over sunitinib. Level of evidence: I. Grade of recommendation: A.
- Given its superiority on PFS over sunitinib, the combination of avelumab + axitinib is an alternative when other combinations are not available. Level of evidence: I. Grade of recommendation: B.
- Sunitinib, pazopanib, and tivozanib are reasonable options when the above-mentioned combinations are not available. Level of evidence: I. Grade of recommendation: B.

PRIMERA LÍNEA CÁNCER RENAL METASTÁSICO

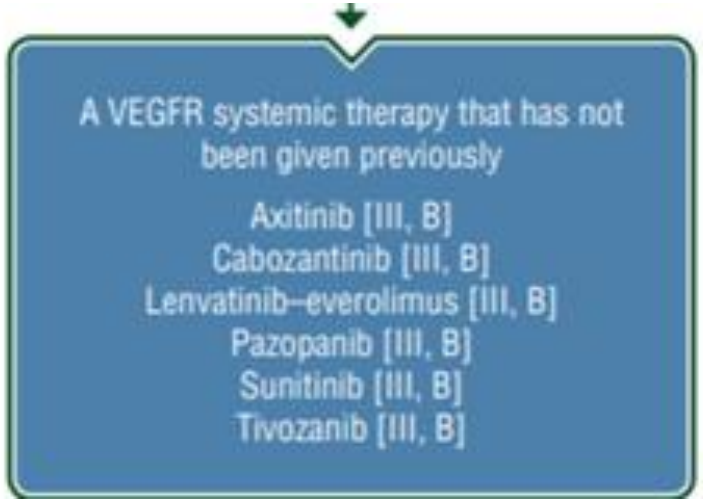
Fig. 1 Advanced mccRCC First Line treatment. See text for levels of evidence



SEGUNDA LÍNEA CÁNCER RENAL METASTÁSICO

Recommendations

- In patients with advanced RCC previously treated with one or two antiangiogenic tyrosine-kinase inhibitors, nivolumab, and cabozantinib are the recommended options. Level of evidence: I. Grade of recommendation: A. Decisions to use either agent may be based on the expected toxicity and on contraindications for each drug, as randomized data is lacking.
- Axitinib, everolimus, lenvatinib + everolimus, and tivozanib are alternatives for second-line, providing that they are available and patients cannot receive nivolumab or cabozantinib. Level of evidence: I. Grade of recommendation: B. In addition, they may also be acceptable options following nivolumab and cabozantinib. Level of evidence: III. Grade of recommendation: C.
- For patients who progress after initial immunotherapy-based treatment, we suggest treatment with an anti-VEGFR TKI. Options include cabozantinib, axitinib, tivozanib, sunitinib, and pazopanib. Further research is required in this context. Level of evidence: III. Grade of recommendation: C.
- Patients should be encouraged to participate in clinical trials whenever possible.



CÁNCER RENAL METASTÁSICO NO CEL CLARAS

Recommendations

- Clinical data are limited in nccRCC, which are usually excluded from controlled phase III trials. Therefore, enrolment into specific clinical trials is strongly recommended. Level of evidence: V. Grade of evidence: A.
- There are no available data regarding post-nephrectomy adjuvant treatment in localized nccRCC.
- In the first-line setting, the most robust data exist for sunitinib, although other targeted therapies, such as TKI and mTOR have limited data. While specific data are not available, the choice of treatment should be based on each specific subtype:

  - **Papillary**: Sunitinib: Level of evidence: II. Grade of evidence: B. Pazopanib: Level of evidence: III. Grade of evidence: C. Everolimus: Level of evidence: II. Grade of evidence: C. Cabozantinib: Level of evidence: IV. Grade of evidence: c.
  - **Cromophobe**: Sunitinib: Level of evidence: II. Grade of evidence: C. Pazopanib: Level of evidence: III. Grade of evidence: C. Everolimus: Level of evidence: II. Grade of evidence: C.
  - **Collecting duct/Medullary**: Cisplatin or carboplatin- based regimen: Level of evidence: III. Grade of evidence: C.
  - **Sarcomatoid**: Sunitinib. Level of evidence: II. Grade of evidence: B. Pazopanib: Level of evidence: III. Grade of evidence: C. Nivolumab+ipilimumab: Level of evidence: IV. Grade of evidence: C.

- After first-line, no recommendation is possible based on available data.

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CLINICAL GUIDES IN ONCOLOGY

SEOM SOGUG clinical guideline for treatment of kidney cancer (2022)

María José Méndez-Vidal[1] · Martin Lázaro Quintela[2] · Nuria Lainez-Milagro[3] · Begoña Perez-Valderrama[4] · Cristina Suárez Rodriguez[5] · José Ángel Arranz Arija[6] · Ignacio Peláez Fernández[7] · Enrique Gallardo Díaz[8] · Julio Lambea Sorrosal[9] · Aránzazu González-del-Alba[10]

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ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

ANNALS OF ONCOLOGY driving innovation in oncology

SPECIAL ARTICLE

ESMO Clinical Practice Guideline update on the use of immunotherapy in early stage and advanced renal cell carcinoma

T. Powles[1], L. Albiges[2], A. Bex[3,4], V. Grünwald[5], C. Porta[6,7], G. Procopio[8], M. Schmidinger[9], C. Suárez[10] & G. de Velasco[11], on behalf of the ESMO Guidelines Committee*

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