

Innovando en el abordaje multidisciplinar del cáncer de próstata en Andalucía

Málaga, 27 de septiembre de 2023

Organizado por:

En colaboración con:

saom
Sociedad andaluza
de oncología médica



Avances en el diagnóstico y seguimiento del cáncer de próstata, el papel del PET-PSMA

Antonio L. Gutiérrez Cardo

Medicina Nuclear

Hospital Regional Universitario de Málaga



Estadificación inicial con PSMA

• PSMA: ESTADIFICACIÓN T

- La RMmp continúa siendo la técnica de referencia
- PSMA: Mejora significativa respecto a técnicas convencionales
- No incluido en Guías
- Rentabilidad cercana al 100% en PET-RMmp

No supone una ventaja frente a RMmp a nivel local

Pero...

Diagnostic Performance of Prostate-specific Membrane Antigen Positron Emission Tomography–targeted biopsy for Detection of Clinically Significant Prostate Cancer: A Systematic Review and Meta-analysis

Tatsushi Kawada^{a,b}, Takafumi Yanagisawa^{a,c}, Pawel Rajwa^{a,d}, Reza Sari Motlagh^{a,e}, Hadi Mostafaei^{a,f}, Fahad Quhal^{a,g}, Ekaterina Laukhtina^{a,h}, Abdulmajeed Aydh^{a,i}, Frederik König^{a,j}, Maximilian Pallauf^{a,k}, Benjamin Pradere^a, Francesco Ceci^{l,m}, Pascal A.T. Baltzerⁿ, Marcus Hacker^o, Sazan Rasul^o, Pierre I. Karakiewicz^p, Motoo Araki^b, Yasutomo Nasu^b, Shahrokh F. Shariat^{a,h,q,r,s,t,u,*}

- Tiene un valor adicional a la RMmp
- Especialmente en PI-RADS 3

Sensitivity	Specificity	PPV	NPV
0.69	0.73	0.48	0.86

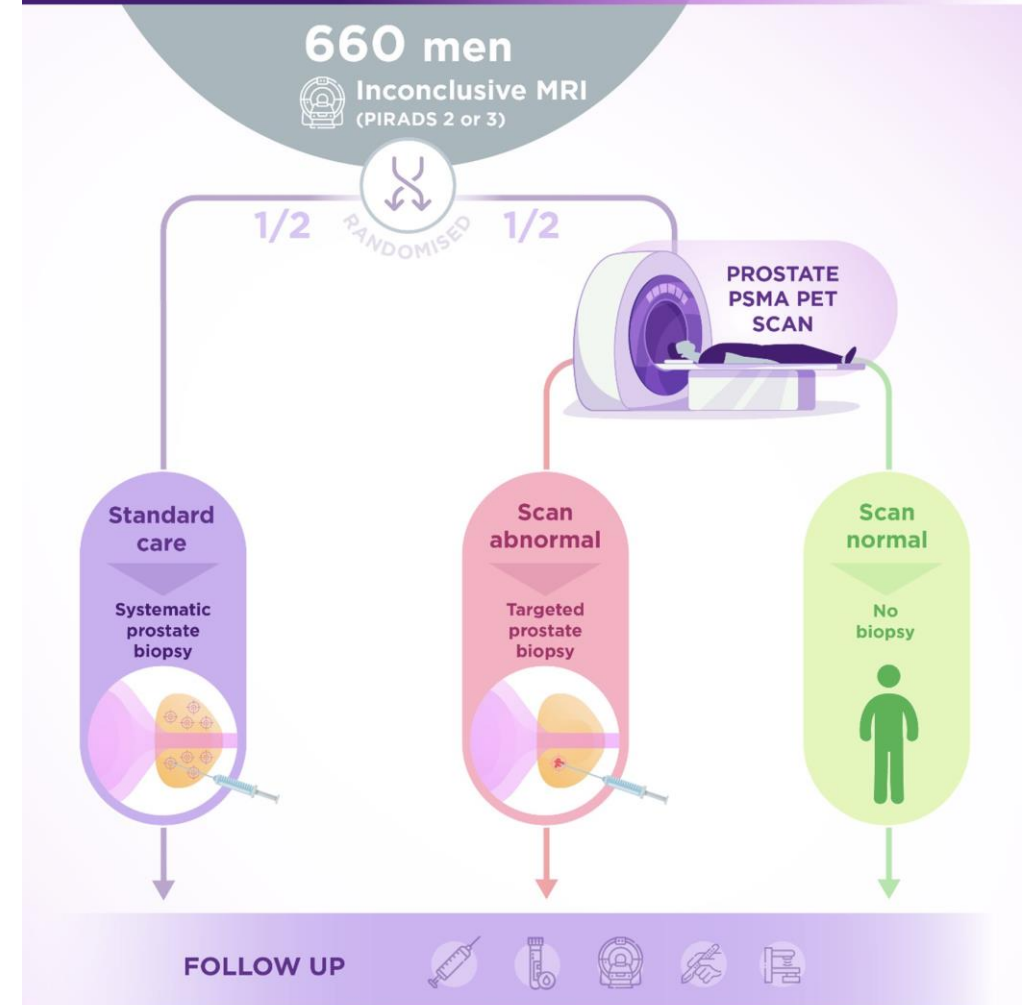


- Ensayo clínico aleatorizado
- RM no concluyente PIRADS 2 o 3
- Randomización ½
 - Biopsia estándar
 - Biopsia guiada por PET

<http://primary2.com>

PRIMARY 2 Clinical trial

Schema



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Estadificación
N y M

¿Qué dicen las guías?
ALTO RIESGO

Table 4.2: EAU risk groups for biochemical recurrence of localised and locally advanced prostate cancer

Definition			
Low-risk	Intermediate-risk	High-risk	
PSA < 10 ng/mL and GS < 7 (ISUP grade 1) and cT1-2a	PSA 10-20 ng/mL or GS 7 (ISUP grade 2/3) or cT2b	PSA > 20 ng/mL or GS > 7 (ISUP grade 4/5) or cT2c	any PSA any GS (any ISUP grade) cT3-4 or cN+
Localised		Locally advanced	

GS = Gleason score; ISUP = International Society for Urological Pathology; PSA = prostate-specific antigen.



NCCN Guidelines Version 1.2023 Prostate Cancer

[NCCN](#)

INITIAL RISK STRATIFICATION AND STAGING WORKUP FOR CLINICALLY LOCALIZED DISEASE^e

Risk Group	Clinical/Pathologic Features See Staging (ST-1)		Additional Evaluation ^{h,i}
Very low ^f	Has all of the following: <ul style="list-style-type: none"> • cT1c • Grade Group 1 • PSA <10 ng/mL • Fewer than 3 prostate biopsy fragments/cores positive, ≤50% cancer in each fragment/core^g • PSA density <0.15 ng/mL/g 		<ul style="list-style-type: none"> • Confirmatory testing can be used to assess the appropriateness of active surveillance (See PROS-F 2 of 5)
Low ^f	Has all of the following but does not qualify for very low risk: <ul style="list-style-type: none"> • cT1–cT2a • Grade Group 1 • PSA <10 ng/mL 		<ul style="list-style-type: none"> • Confirmatory testing can be used to assess the appropriateness of active surveillance (See PROS-F 2 of 5)
Intermediate ^f	Favorable intermediate	Has all of the following: <ul style="list-style-type: none"> • 1 IRF • Grade Group 1 or 2 • <50% biopsy cores positive (eg, <6 of 12 cores)^g 	<ul style="list-style-type: none"> • Confirmatory testing can be used to assess the appropriateness of active surveillance (See PROS-F 2 of 5)
	Unfavorable intermediate	Has one or more of the following: <ul style="list-style-type: none"> • 2 or 3 IRFs • Grade Group 3 • ≥ 50% biopsy cores positive (eg, ≥ 6 of 12 cores)^g 	Bone and soft tissue imaging ^{j,k} <ul style="list-style-type: none"> • If regional or distant metastases are found, see PROS-8 or PROS-12
High	Has no very-high-risk features and has exactly one high-risk feature: <ul style="list-style-type: none"> • cT3a OR • Grade Group 4 or Grade Group 5 OR • PSA >20 ng/mL 		Bone and soft tissue imaging ^{j,k} <ul style="list-style-type: none"> • If regional or distant metastases are found, see PROS-8 or PROS-12
Very high	Has at least one of the following: <ul style="list-style-type: none"> • cT3b–cT4 • Primary Gleason pattern 5 • 2 or 3 high-risk features • >4 cores with Grade Group 4 or 5 		Bone and soft tissue imaging ^{j,k} <ul style="list-style-type: none"> • If regional or distant metastases are found, see PROS-8 or PROS-12

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¿Seguimos usando
GO+TAC?



Estadificación convencional

• GAMMAGRAFÍA ÓSEA: M

- Sensibilidad 79%
- Especificidad 82%

- Realizar en todo paciente sintomático

• TAC: N+M

- N: Sensibilidad 40%
Especificidad 82%
- M: Sensibilidad 56%
Especificidad 74%

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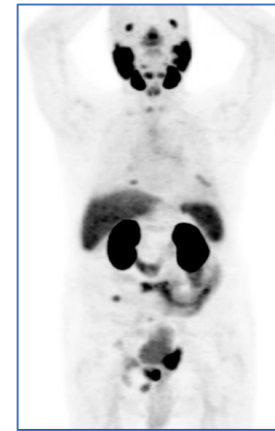
Málaga, 27 de **septiembre** de 2023

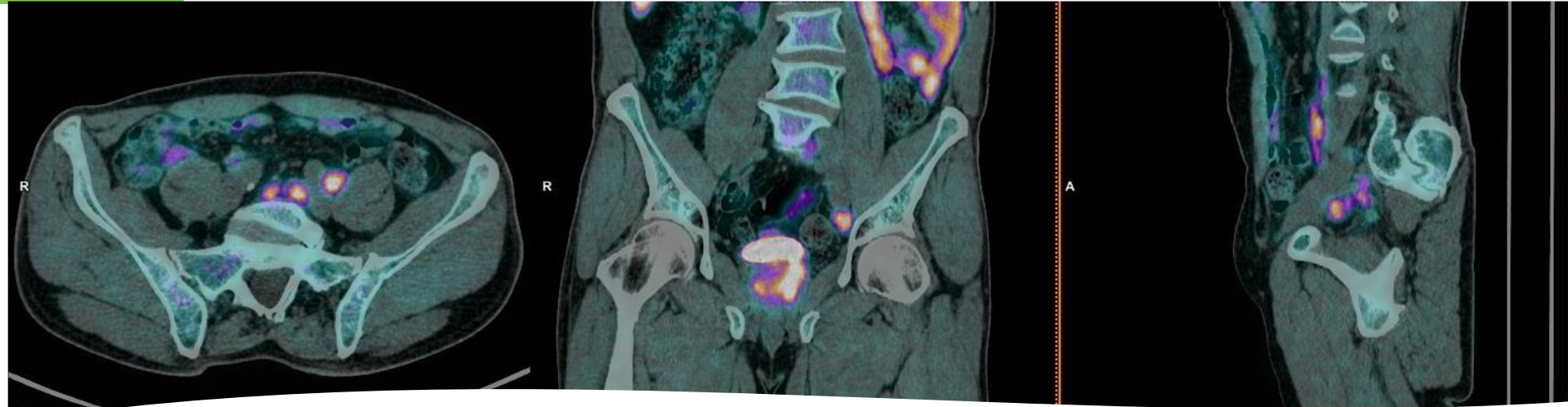
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¿Y las NGIs?





PET Colina

Estadificación N

- Metaanálisis n: 609 p
 - S 62 % (51-66%_{ic 95%})
 - E 92 % (89-94%_{ic 95%})
- La sensibilidad es mayor en alto riesgo
 - 50% en alto riesgo
 - 71% en muy alto riesgo
 - Mejor en comparación con TAC
 - Sin ventajas evidentes frente a RM wb

PET Colina

Estadificación M

- No está claro si es más sensible que la GO
- Mayor especificidad
- Menor número de lesiones indeterminadas
- Detección de metástasis viscerales

Table 5 Overview of performance of ^{18}F -DCFPyl PET/CT in detecting lymph node metastases as was studied by the SALT-trial, ^{68}Ga -PSMA-PET/CT by the PEPPER-trial in comparison to ^{18}F -PSMA-1007 PET/CT

		% (95% CI)			
		Sensitivity	Specificity	Positive predictive value	Negative predictive value
^{18}F -PSMA-1007 PET/CT	Patient based	53.3 (34.3–71.7)	89.9 (80.2–95.8)	69.6 (51.2–83.3)	81.6 (75.0–86.8)
	Side based	41.3 (27.0–56.8)	94.1 (89.1–97.3)	67.9 (50.7–81.3)	84.1 (80.6–87.1)
	4-template based	20.5 (9.8–35.3)	94.0 (91.0–96.3)	30.0 (17.3–46.7)	90.5 (89.1–91.7)
	12-template based	12.9 (5.7–23.9)	97.7 (96.6–98.5)	23.5 (12.7–39.5)	95.3 (94.9–95.7)
^{18}F -DCFPyl PET/CT (SALT) [8]	Patient based	41.2 (19.4–66.5)	94.0 (86.9–97.5)	53.8 (26.1–79.6)	90.4 (82.6–95.0)
	Template based	34.7 (17.1–57.1)	97.7 (95.7–98.9)	44.4 (22.4–68.6)	96.6 (94.4–98.0)
^{68}Ga -PSMA-PET/CT (PEPPER) [7]	Patient based	41.5 (26.7–57.8)	90.9 (79.3–96.6)	77.3 (54.2–91.3)	67.6 (55.6–77.7)
	Template based	35.1 (23.2–48.9)	96.4 (93.5–98.1)	64.5 (45.4–80.2)	89.0 (85.0–92.0)
^{18}F -DCFPyl [5]	Patient based	40.3 (28.1–52.5)	97.9 (94.5–99.4)	86.7 (69.7–95.3)	83.2 (78.2–88.1)
^{68}Ga -PSMA-11 [6]	Patient based	40.0 (34.0–46.0)	95.0 (90.2–97.0)	75.0 (70.0–80.0)	81.0 (76.0–85.0)

Can Negative Prostate-specific Membrane Antigen Positron Emission Tomography/Computed Tomography Avoid the Need for Pelvic Lymph Node Dissection in Newly Diagnosed Prostate Cancer Patients? A Systematic Review and Meta-analysis with Backup Histology as Reference Standard

Conclusions: PSMA PET/CT scan provides promising accuracy in the field of primary nodal staging for PCa. The high NPV in men with a lower risk of LNI might be clinically useful to reduce the number of unnecessary PLND procedures performed. Conversely, in high-risk patients, negative PSMA PET/CT cannot replace staging ePLND.

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Málaga, 27 de septiembre de 2023

PSMA PET/CT estadificación de alto riesgo

- Alta S y E en adenopatías y metástasis
- Alta precisión
- Cambio del manejo terapéutico
 - Planificación de radioterapia
 - Enfoque quirúrgico

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ProPSMA diagnostic phase 3 randomised study

Prostate Specific Membrane Antigen (PSMA) PET/CT

for imaging men with newly diagnosed prostate cancer

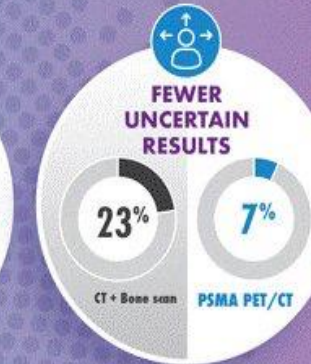
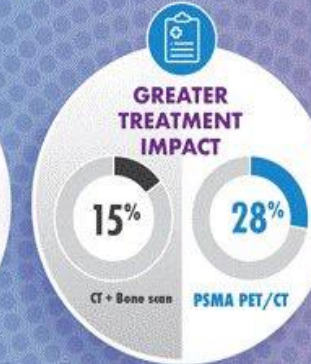
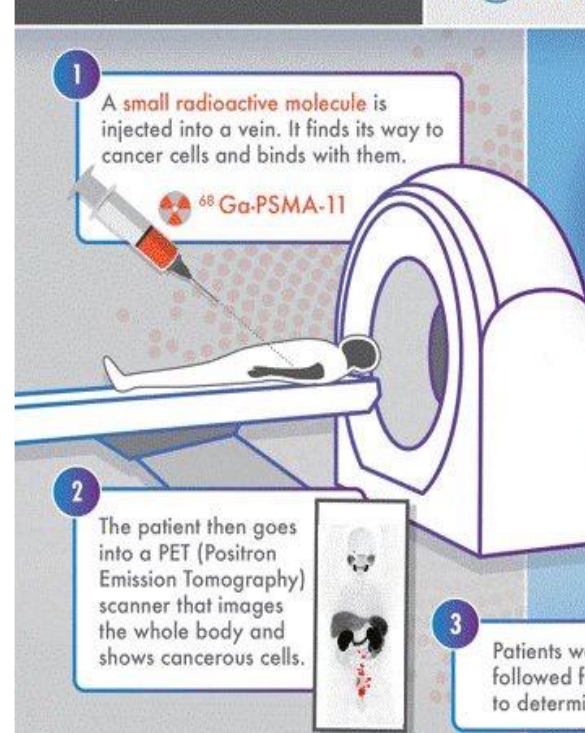
302 patients, randomised with untreated prostate cancer

10 sites across Australia

50% current method: CT + Bone scan

50% studied method: PSMA PET/CT

The data supports PSMA PET/CT imaging as a replacement to current standard-of-care CT and bone scan.



OTHER FINDINGS:



Research sponsored by:



and proudly funded by:

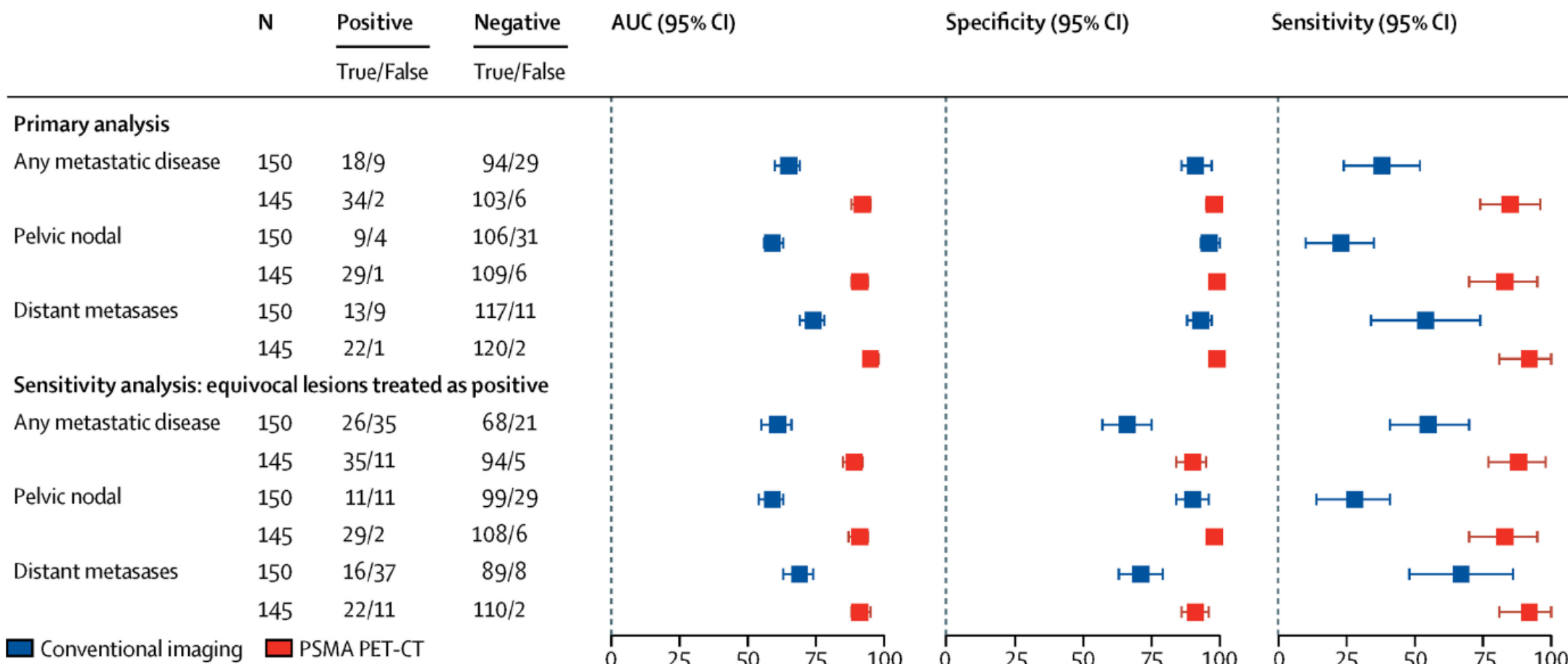


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Málaga, 27 de septiembre de 2023

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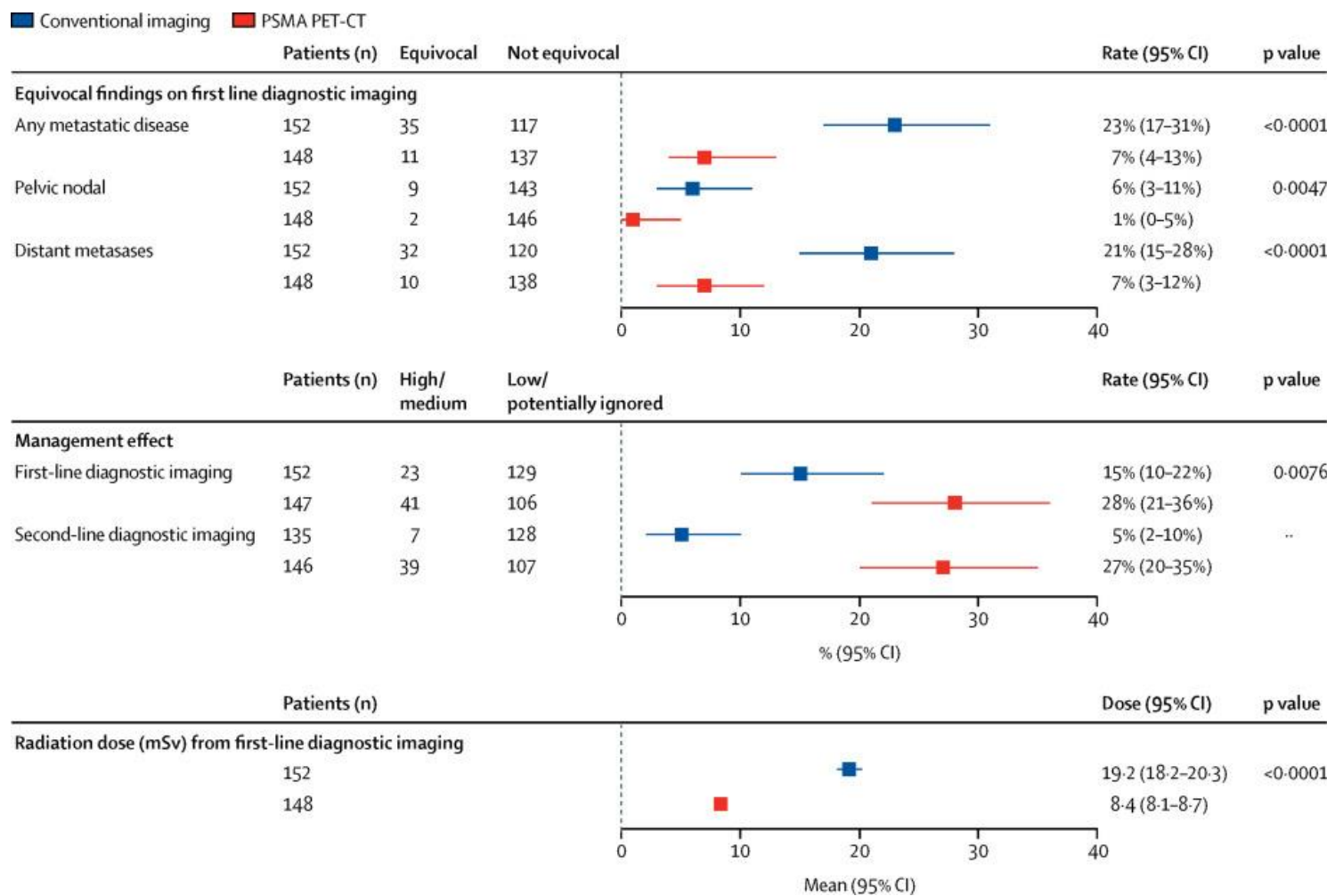
proPSMA Hofman et al. Prostate-specific membrane antigen PET-CT in patients with high-risk prostate cancer before curative-intent surgery or radiotherapy (proPSMA): a prospective, randomised, multicentre study. Lancet. 2020 Apr 11;395(10231):1208–16.

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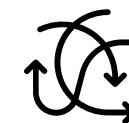
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Resultados EQUÍVOCOS



Cambio MANEJO



Dosis Radiación



proPSMA Hofman et al. Prostate-specific membrane antigen PET-CT in patients with high-risk prostate cancer before curative-intent surgery or radiotherapy (proPSMA): a prospective, randomised, multicentre study. *Lancet*. 2020 Apr 11;395(10231):1208–16.

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2022

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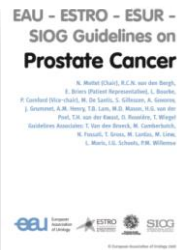
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5.3.5 Summary of evidence and guidelines for staging of prostate cancer

Summary of evidence	LE
PSMA PET/CT is more accurate for staging than CT and bone scan for high-risk disease but to date no outcome data exist to inform subsequent management.	1b

Recommendations	Strength rating
Any risk group staging	
Use pre-biopsy MRI for local staging information.	Weak
Low-risk localised disease	
Do not use additional imaging for staging purposes.	Strong
Intermediate-risk disease	
In ISUP grade 3, include at least cross-sectional abdominopelvic imaging and a bone-scan	Weak
High-risk localised disease/locally advanced disease	
Perform metastatic screening including at least cross-sectional abdominopelvic imaging and a bone-scan.	Strong
When using PSMA PET or whole body MRI to increase sensitivity, be aware of the lack of outcome data of subsequent treatment changes.	Strong

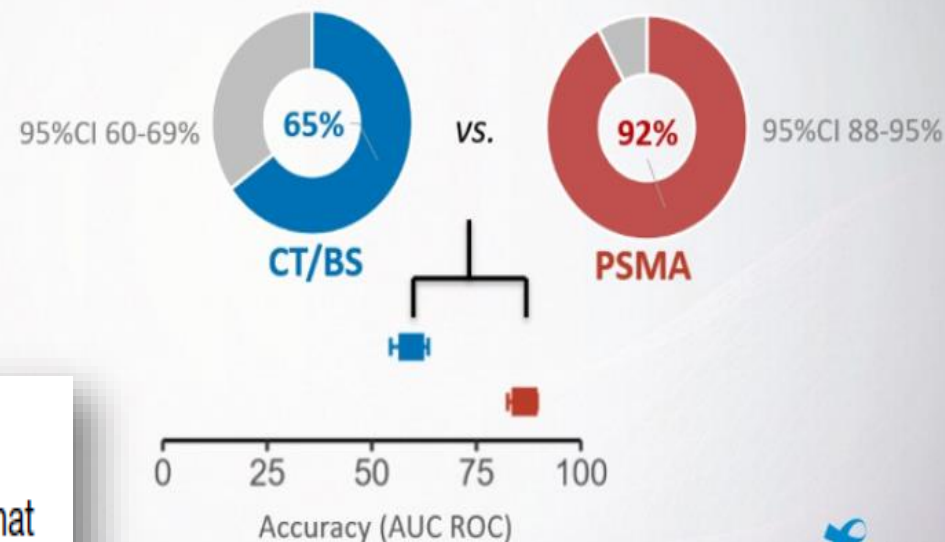


Primary outcome



PSMA PET/CT 27% greater accuracy than conventional imaging

95% CI 23-31%; p < 0.001



5.3.4 Summary of evidence and practical considerations on initial N/M staging

The field of non-invasive N- and M-staging of PCa patients is evolving very rapidly. Evidence shows that choline PET/CT, PSMA PET/CT and whole-body MRI provide a more sensitive detection of LN- and bone metastases than the classical work-up with bone scan and abdominopelvic CT. In view of the evidence offered by the randomised, multi-centre proPSMA trial [465], replacing bone scan and abdominopelvic CT by more sensitive imaging modalities may be a consideration in patients with high-risk PCa undergoing initial staging.

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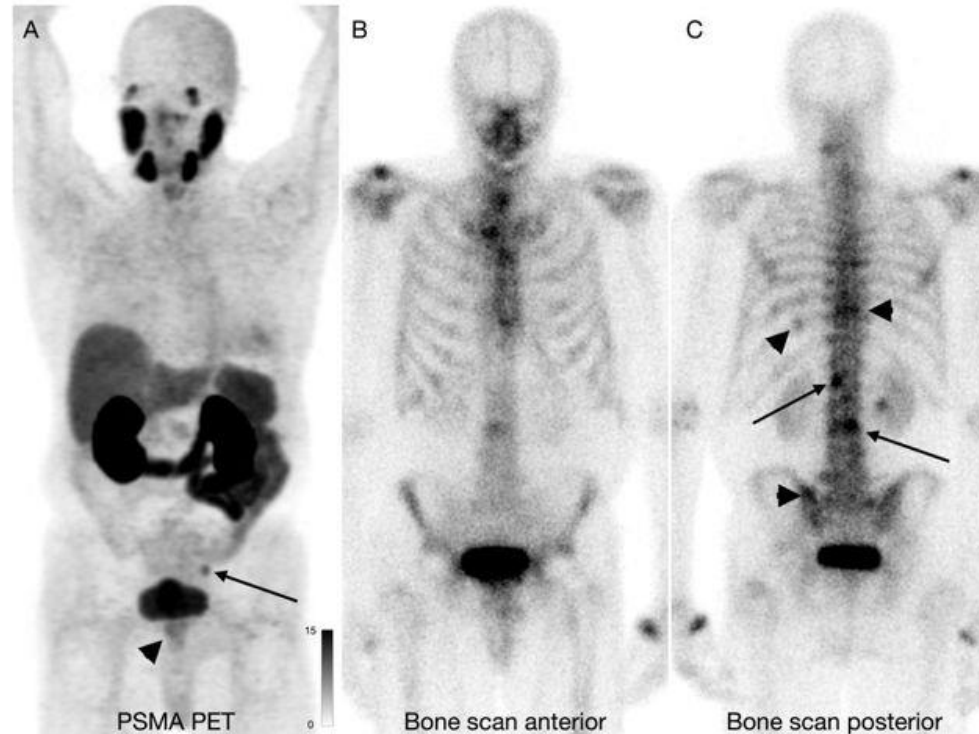
Do Bone Scans Over Stage Disease Compared to PSMA PET at Initial Staging?

We compared interpretations of bone scans and PSMA PETs in 167 patients to determine the PPV of bone scans at various stages of disease

BS results	Initial staging	BCR	CRPC
PPV	0.43	0.77	1.00
NPV	0.94	0.74	0.56
Specificity	0.80	0.85	1.00

Of the 23 patients positive on bone scan, only 10 were positive on PSMA PET at initial staging...

Bone scans over stage patients at initial staging relative to PSMA PET



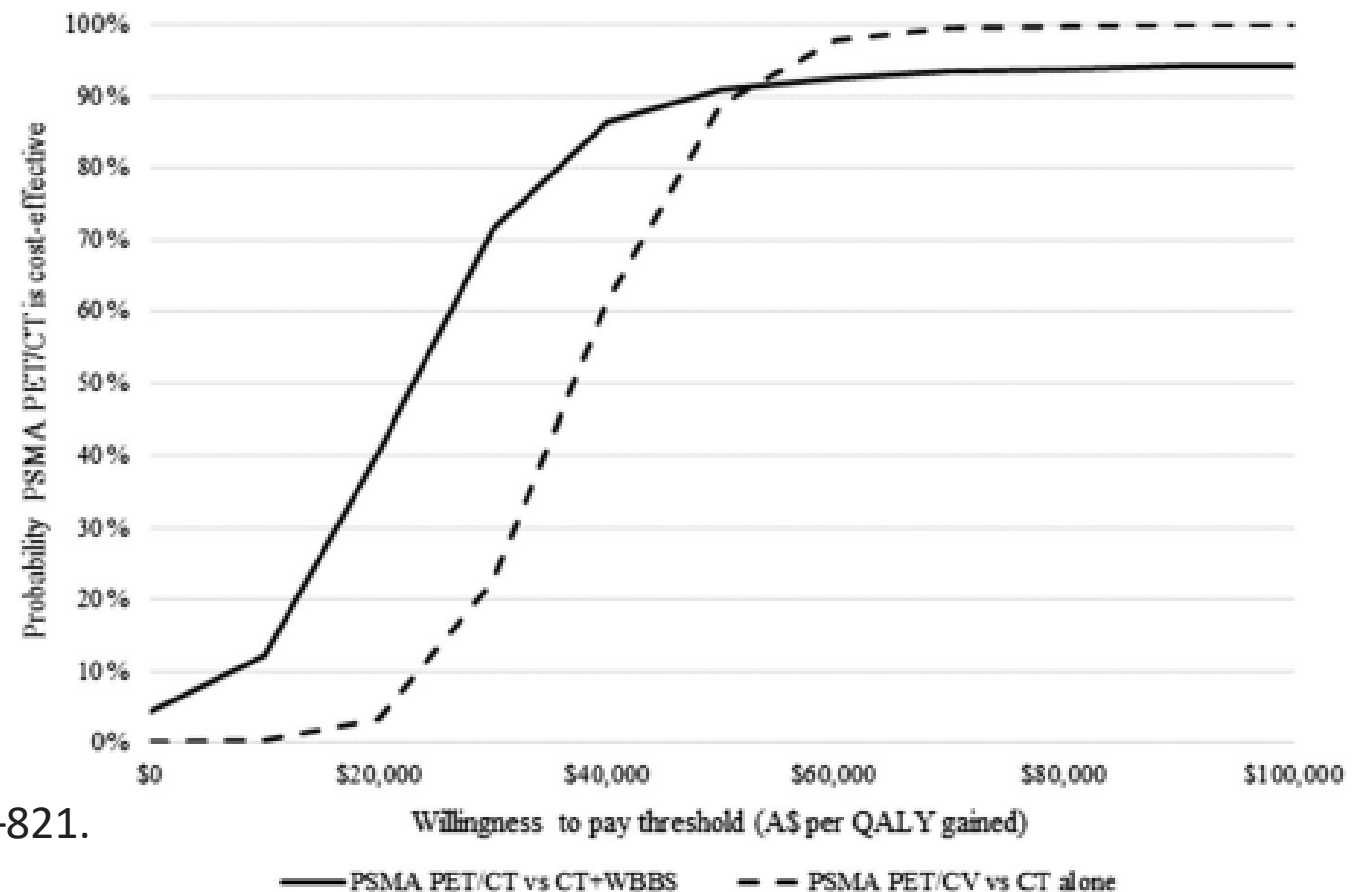
Patient with bone scan showed osseous metastases and PSMA PET was negative in the bones


57% FALSOS POSITIVOS
GO en estadificación

PSMA costo-efectividad

- Diagnóstico reciente
- Riesgo intermedio o alto
- Comparación vs TAC o vs TAC+GO

- No ahorra costes
- Coste-efectivo frente a todos los comparadores



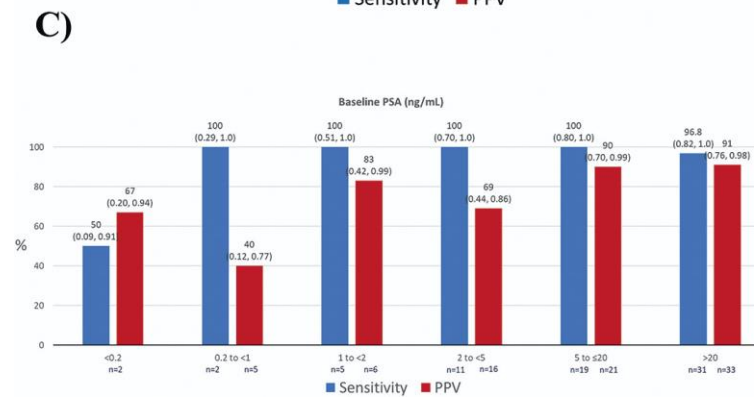
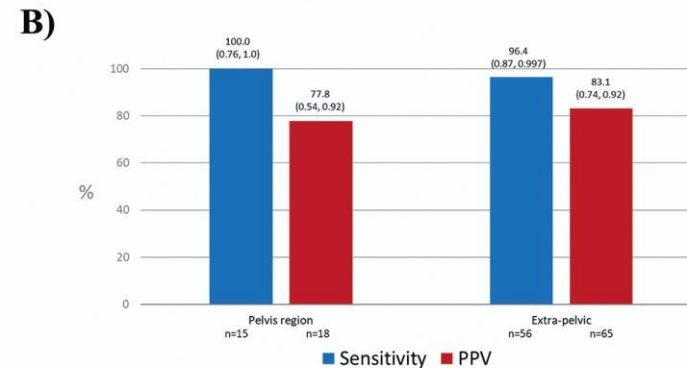
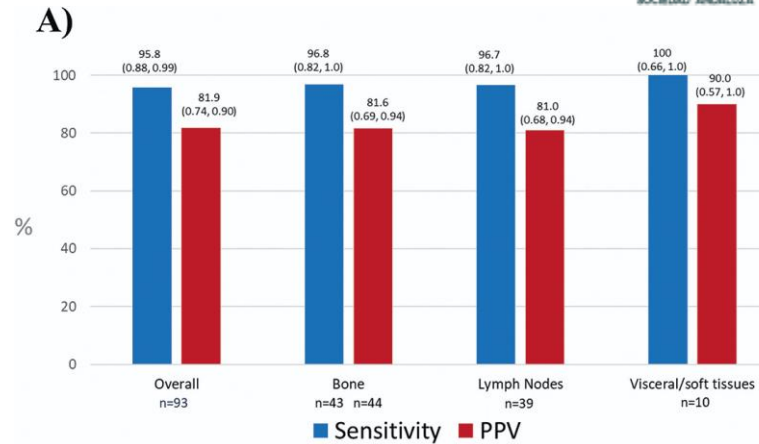


Diagnóstico de recidiva con PSMA

Pacientes con opciones de terapia radical

- PET-TAC PSMA es más sensible que Colina
- Especialmente para niveles bajos de PSA (<0.5 ng/mL)
- Supera al resto de técnicas de imagen en el diagnóstico de metástasis
- Valoración de recurrencia local adicional a RM

OSPNEY
Pienta *J Urol* 2021



- Cohorte recidiva bioquímica
- Sensibilidad y VPP
- Comparador: anatomía patológica en:
 - Sitios metastásicos
 - Metástasis por región
 - Por rangos de PSA

Metaanalysis of ^{68}Ga -PSMA-11 PET Accuracy for the Detection of Prostate Cancer Validated by Histopathology

Thomas A. Hope¹⁻⁴, Jeremy Z. Goodman⁴, Isabel E. Allen⁵, Jeremie Calais⁶, Wolfgang P. Fendler⁷, and
Peter R. Carroll^{3,4}

Recurrencia bioquímica

- **Sensibilidad 74%** (95% IC 0.51–0.89)
- **Especificidad 96%** (95% CI 0.85–0.99)
- Gold standard: histopatología ganglionar
- VPP 99% (95% CI 0.96–1.00)
- Tasa de detección:
 - PSA <2.0 ng/mL 0.63 (95% CI, 0.55–0.70)
 - PSA >2.0 ng/mL 0.94 (95% CI, 0.91–0.96)

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Nivel PSA (ng/mL)	Registro FDA PSMA11	CONDOR DCFPyL	PYTHON DCFPyL
<0.5	38%	35	35%
0.5-<1.0	57%	50	54%
1.0-<2.0	84%	68	68%
>2.0	86% (>5: 97%)	90	87%

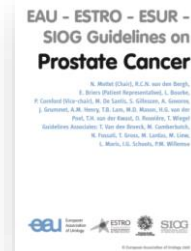
Fendler *JAMA Oncol* 2019

Morris *Clin Cancer Res* 2021

Oprea-Lager *Eur J Nucl Med Mol Imaging* 2023

6.3.4.4 Summary of evidence and guidelines for imaging in patients with biochemical recurrence

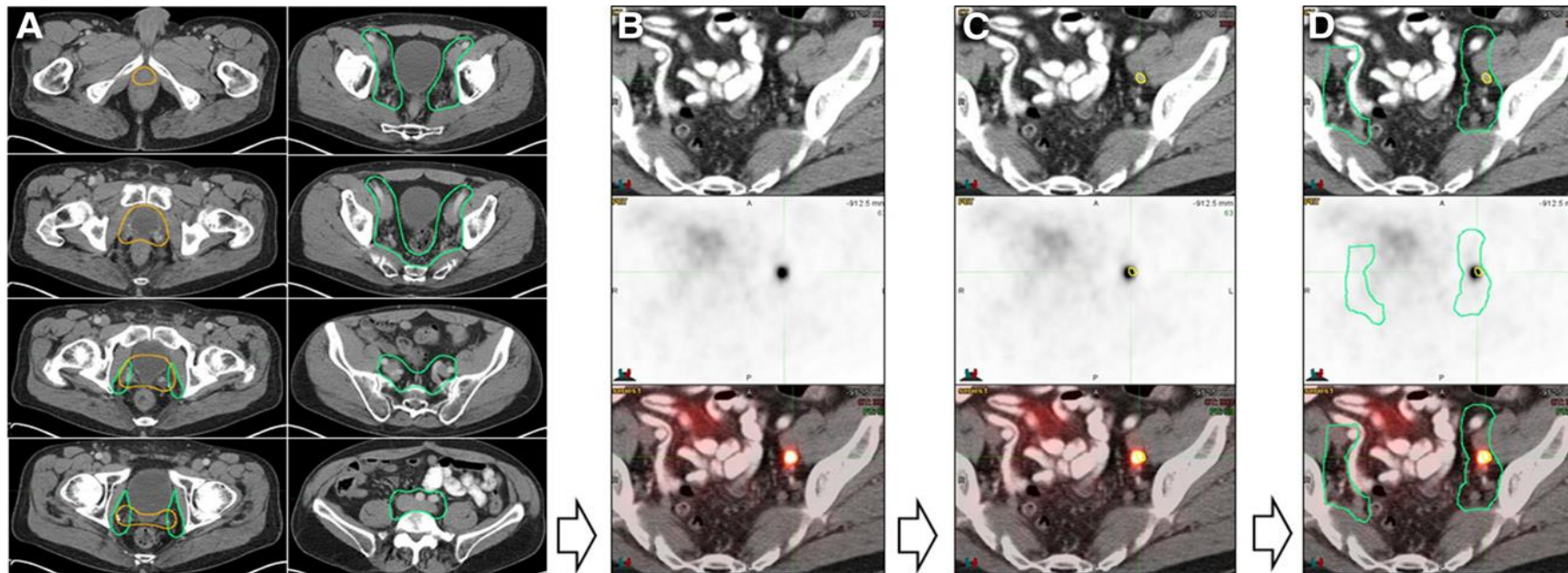
Recommendations	Strength rating
Prostate-specific antigen (PSA) recurrence after radical prostatectomy	
Perform prostate-specific membrane antigen (PSMA) positron emission tomography/computed tomography (PET/CT) if the PSA level is > 0.2 ng/mL and if the results will influence subsequent treatment decisions.	Weak
In case PSMA PET/CT is not available, and the PSA level is ≥ 1 ng/mL, perform fluciclovine PET/CT or choline PET/CT imaging if the results will influence subsequent treatment decisions.	Weak
PSA recurrence after radiotherapy	
Perform prostate magnetic resonance imaging to localise abnormal areas and guide biopsies in patients fit for local salvage therapy.	Weak
Perform PSMA PET/CT (if available) or fluciclovine PET/CT or choline PET/CT in patients fit for curative salvage treatment.	Strong





Planificación terapéutica

- Radioterapia guiada por PET-PSMA



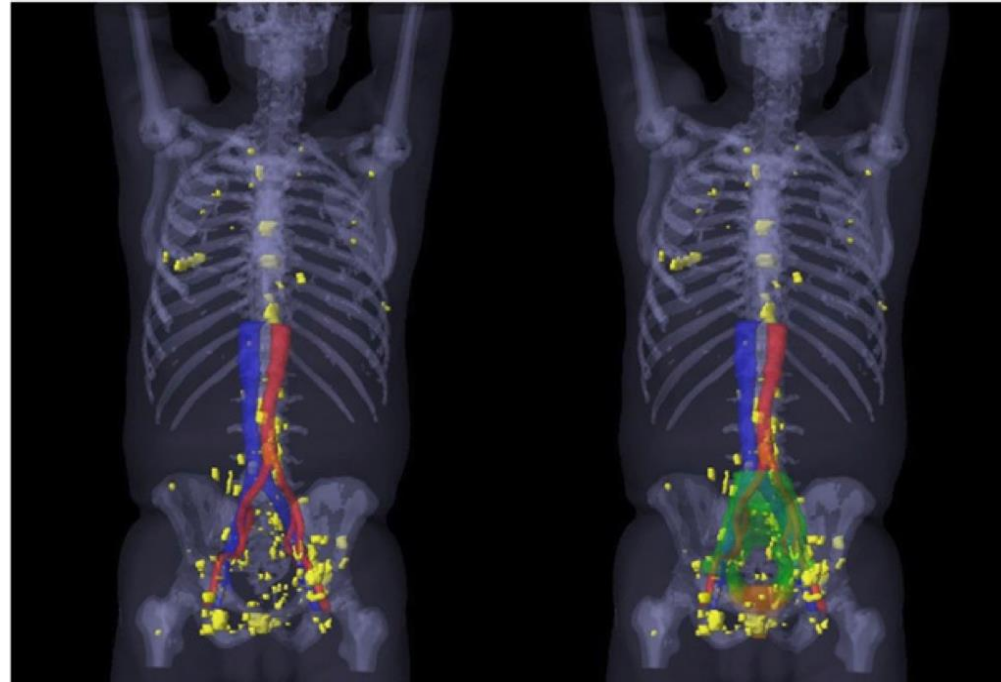
Calais J Nucl Med 2018

¿Los CTVs basados en RTOG cubren la extensión que determina el 68Ga-PSMA? Incluyendo ganglios pélvicos en todos los pacientes.

• Radioterapia guiada por PET-PSMA









Calais J Nucl Med 2018

- 270 pacientes
- 132 PET+ 52/270 (19%) pacientes sin lesiones cubiertas por los CTVs
hueso (44%)
ganglios perirectales (31%)
- 33/270 (12 %) de lesiones extrapélvicas
- 19/270 (7%) lesiones pélvicas no cubiertas por los CTVs



Article

PSMA-PET Guided Treatment in Prostate Cancer Patients with Oligorecurrent Progression after Previous Salvage Treatment

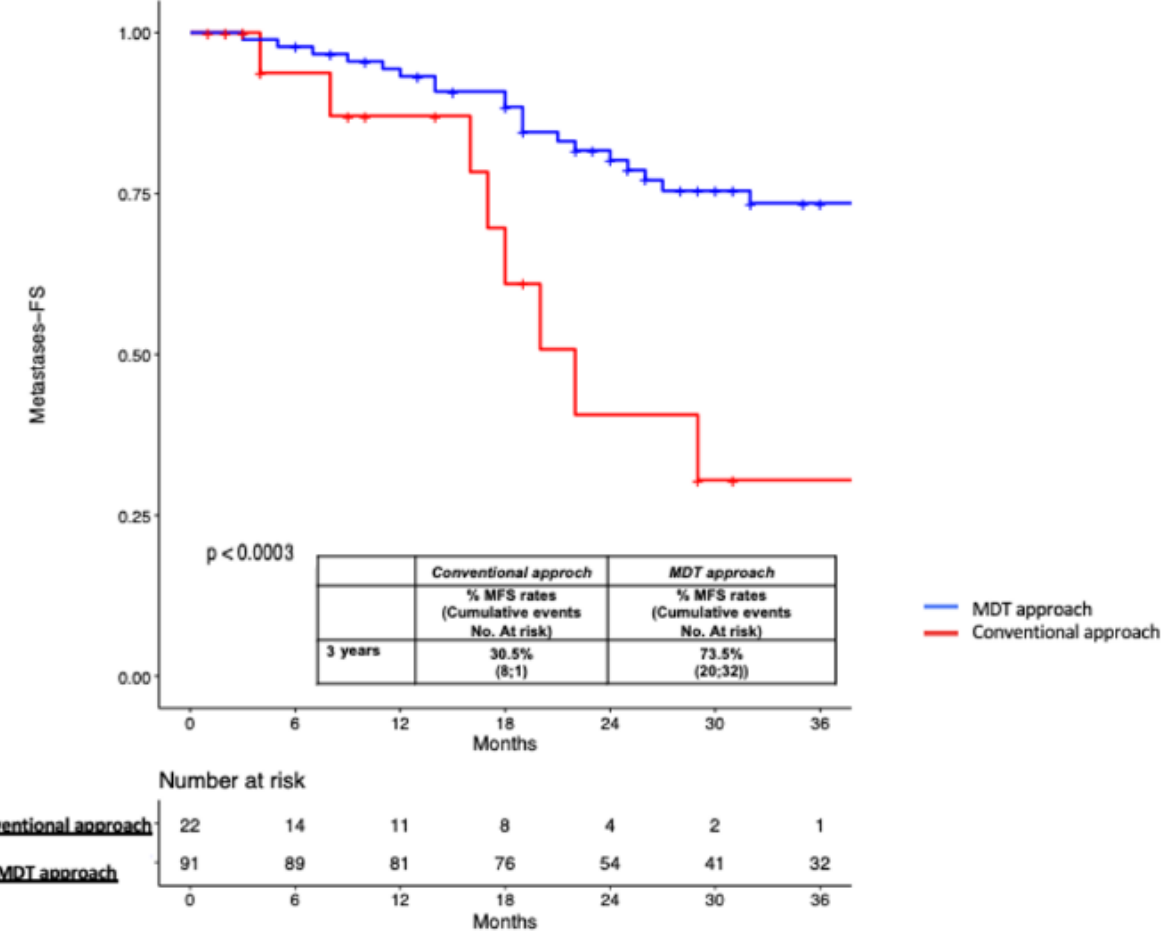
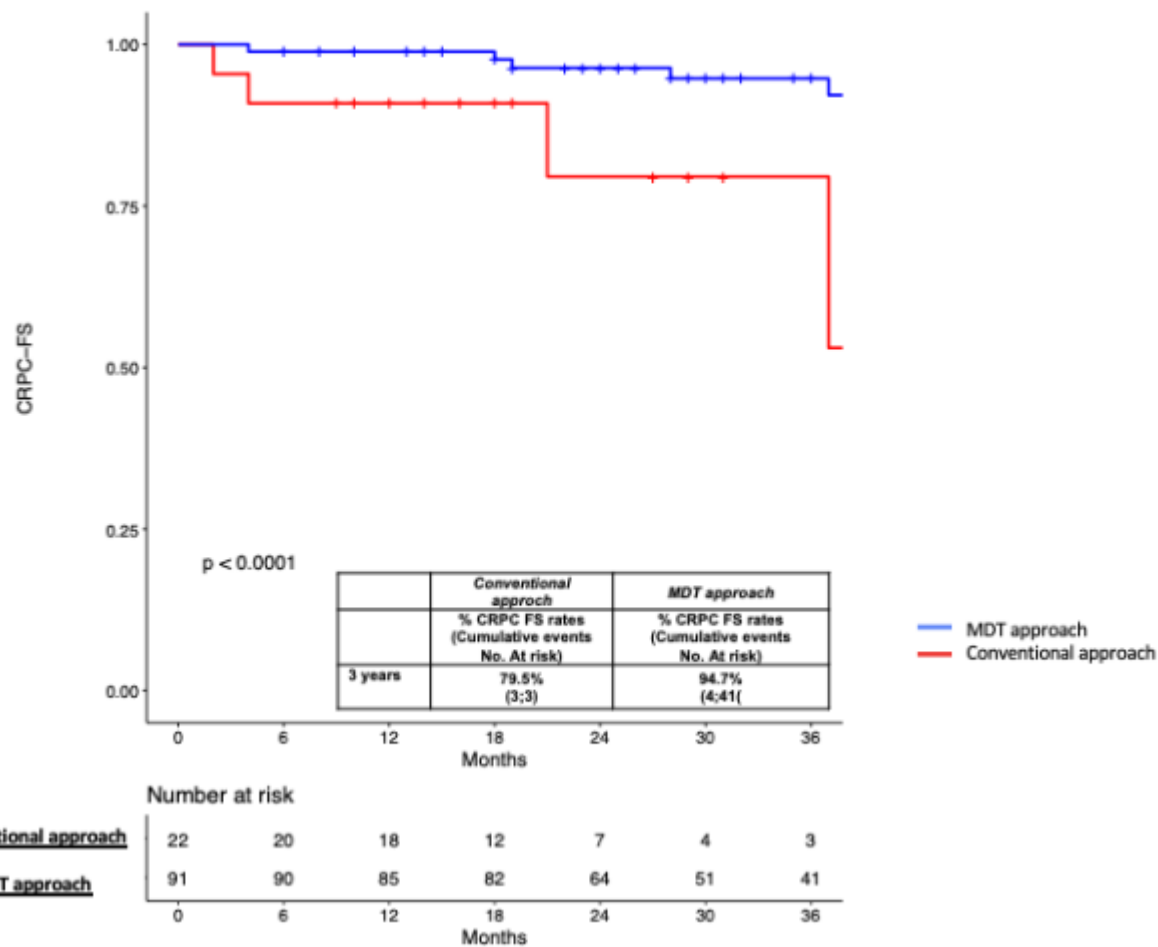
Lorenzo Bianchi ^{1,2,†} , Francesco Ceci ^{3,4,*,†} , Eleonora Balestrazzi ¹, Francesco Costa ¹ , Matteo Droghetti ¹ ,
Pietro Piazza ¹ , Alessandro Pissavini ¹, Massimiliano Presutti ¹, Andrea Farolfi ⁵, Riccardo Mei ⁵ ,
Paolo Castellucci ⁵, Giorgio Gandaglia ⁶, Alessandro Larcher ⁶, Daniele Robesti ⁶, Alexandre Mottrie ^{7,8},
Alberto Briganti ⁶, Alessio Giuseppe Morganti ⁹ , Stefano Fanti ^{2,3} , Francesco Montorsi ⁶, Riccardo Schiavina ^{1,2}
and Eugenio Brunocilla ^{1,2}

Oncologic outcomes of second-line PSMA-guided MDT in PCa patients with PSA progression after previous salvage treatments and oligo-recurrence detected with PSMA-PET

PSMAPET could be used to **personalize second-line salvage therapies** by adopting an MDT approach.

Patients PSMA-guided MDT: **similar PFS and higher MFS and CRPC-FS compared to men who received conventional management.**

High-risk men with oligo-recurrent N1/M1a-b disease and limited therapeutic chances due to previous salvage treatments, the PSMA-PET directed approach with the consolidation of metastatic lesions may represent a promising secondline salvage approach to delay the further progression of disease to CRPC status



PSMAPET could be used to personalize second-line salvage therapies by adopting an MDT approach.

Patients PSMA-guided MDT: similar PFS and higher MFS and CRPC-FS compared to men who received conventional management.

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- Valoración de respuesta

European Journal of Nuclear Medicine and Molecular Imaging (2021) 48:469–476
<https://doi.org/10.1007/s00259-020-04934-4>

ORIGINAL ARTICLE

Consensus statements on PSMA PET/CT response assessment criteria in prostate cancer

Stefano Fanti¹ • Karolien Goffin² • Boris A Hadaschik³ • Ken Herrmann⁴ • Tobias Maurer⁵ • Steven MacLennan⁶ •
Daniela E. Oprea-Lager⁷ • Wim JG Oyen^{8,9,10} • Olivier Rouvière^{11,12} • Nicolas Mottet¹³ • Anders Bjartell¹⁴ 

Received: 27 May 2020 / Accepted: 17 June 2020 / Published online: 2 July 2020
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[BMC Cancer](#). 2019; 19: 18.

Published online 2019 Jan 7. doi: [10.1186/s12885-018-5200-1](https://doi.org/10.1186/s12885-018-5200-1)

PMCID: PMC6322287

PMID: [30616601](https://pubmed.ncbi.nlm.nih.gov/30616601/)

Randomized prospective phase III trial of ^{68}Ga -PSMA-11 PET/CT molecular imaging for prostate cancer salvage radiotherapy planning [PSMA-SRT]

[Jeremie Calais](#),^{✉1} [Johannes Czernin](#),^{✉1} [Wolfgang P. Fendler](#),^{1,2} [David Elashoff](#),³ and [Nicholas Nicholas G. Nickols](#)^{4,5}

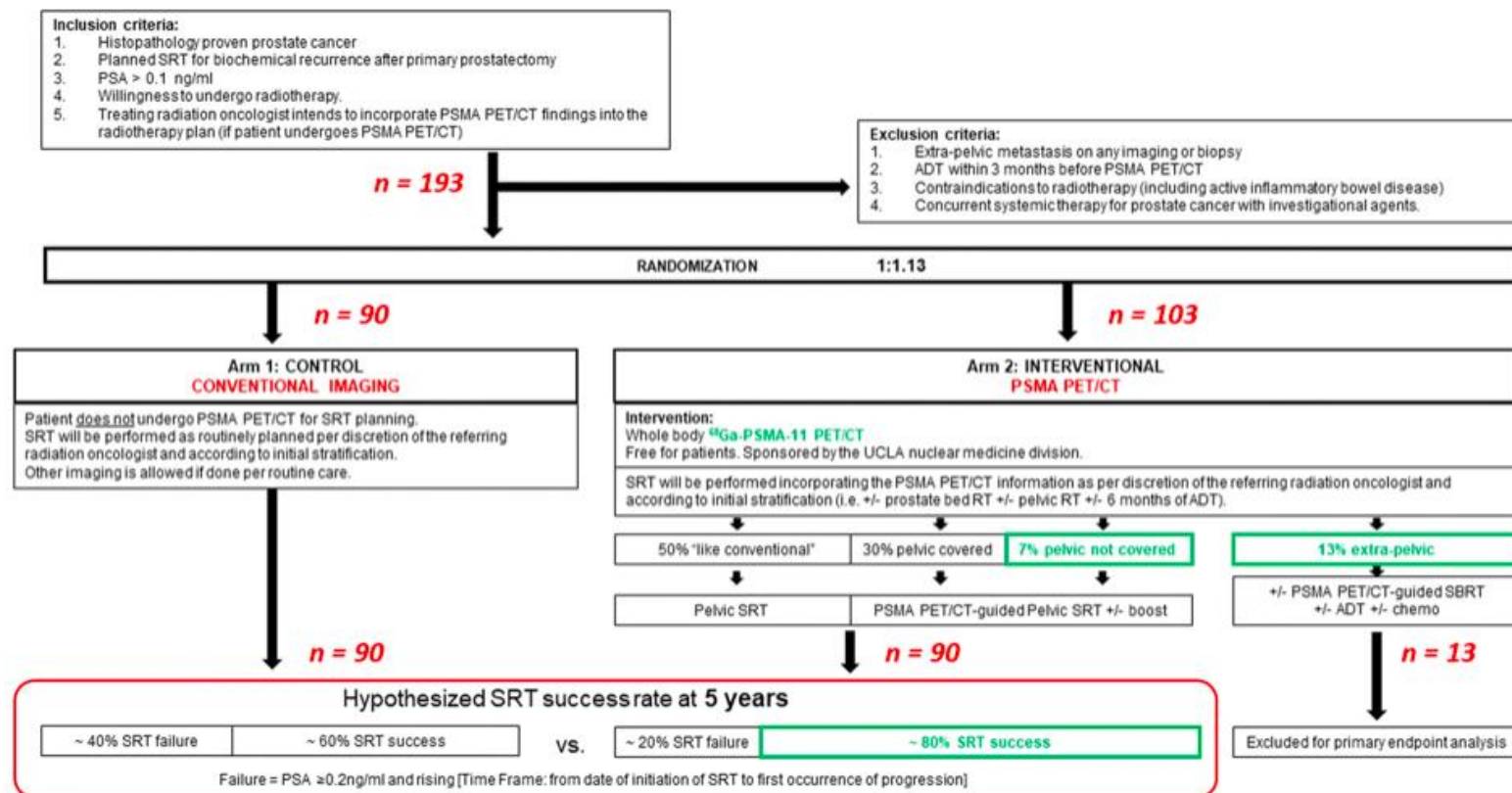
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Demostración del impacto de tratar en base a la extensión por PSMA

Recidiva bioquímica precoz

Seguimiento de 5 años postRT (previsto 2025)

From: [Randomized prospective phase III trial of ⁶⁸Ga-PSMA-11 PET/CT molecular imaging for prostate cancer salvage radiotherapy planning \[PSMA-SRT\]](#)



Study Design. ⁶⁸Ga-: Gallium-68; ADT: Androgen deprivation therapy; PET/CT: Positron Emission tomography/Computed Tomography; PSA: Prostate-specific antigen; PSMA: Prostate-specific membrane antigen; SRT: Salvage Radiation Therapy; SBRT: Stereotactic Body Radiation Therapy; UCLA: University of California, Los Angeles

Tratamiento de la oligorrecurrencia guiada por PET

Table 1. Summary of prospective phase I–II trials of MDT in nodal oligoMET prostate cancer.

Study (Ref)	N	Imaging/ N° MET	Type of Lesion	MDT/ Design	Median FU	Endpoints	Outcome
Harrows (11) SABR-COMET Phase II RCT	16/99	Conv. 1–5		Palliative SOC (PSOC) vs. SABR + PSOC	5.7 yrs	P: OS S: PFS Toxicity, QoL,	8-yr OS: HR 0.50 8-yr PFS: HR. 0.45
Ost (13) STOMP Phase II RCT	62	PET-Cho (1–3)	Nodal 55% M1a 16% 1–2 met 78%	Surveillance vs. MDT: SBRT (81%) or S)	3 yrs	P: ADTF	13 vs. 21 mo (HR 0.60; $p = 0.11$)
Phillips (14) ORIOLE Phase II RCT	4	Conv PSMA-PET (1–3)	Nodal alone 58% mean n° lesions 1.6	Surveillance vs. SBRT	19 mo	6 months PFS Median PFS	81% vs. 39% ($p = 0.005$) HR 0.30; $p = 0.002$)
Siva (17) POPSTAR Phase I	33	CT, BS, F-PET 1–3	Nodal 39% 1 lesion: 67%	SBRT (1 × 20 Gy) (ADT 33%)	24 mo	Local-PFS	2-yr L-PFS 93% 2-yr DFS 39% 2-yr ADTF 48%
Glicksman (16) PSMA MRgRT Phase II	74	PSMA-PET- CT/MR 2 lesions	Nodal 34/37 N1 ≤ 3 in 31/37 M1a: 4	SBRT (87%) or Surgery No ADT	41 mo	P: PSA response S: PSA-PFS and ADTF	51% Median 21 months Median 45 months
Hölscher (18) OLI-P Phase II	63	PSMA-PET/MR 1 lesion	1 lesion: 71% Nodal alone 68%	SBRT 77% CRT 50 Gy 23% No ADT	37 mo	P: Treatment-related toxicity S: PSAFS Time to ADT	No grade ≥ 2 tox Median 13.2 mo Median 20.6 mo
Conde Moreno (48) SBRT- SG05 Phase II	67	PET-Cho/MR 1–5	Nodal 57% Non-spinal bone 36% Spinal bone 6%	SBRT and ADT	41 mo	DPFS	Median DPFS 54.2 mo No grade ≥ 3 tox

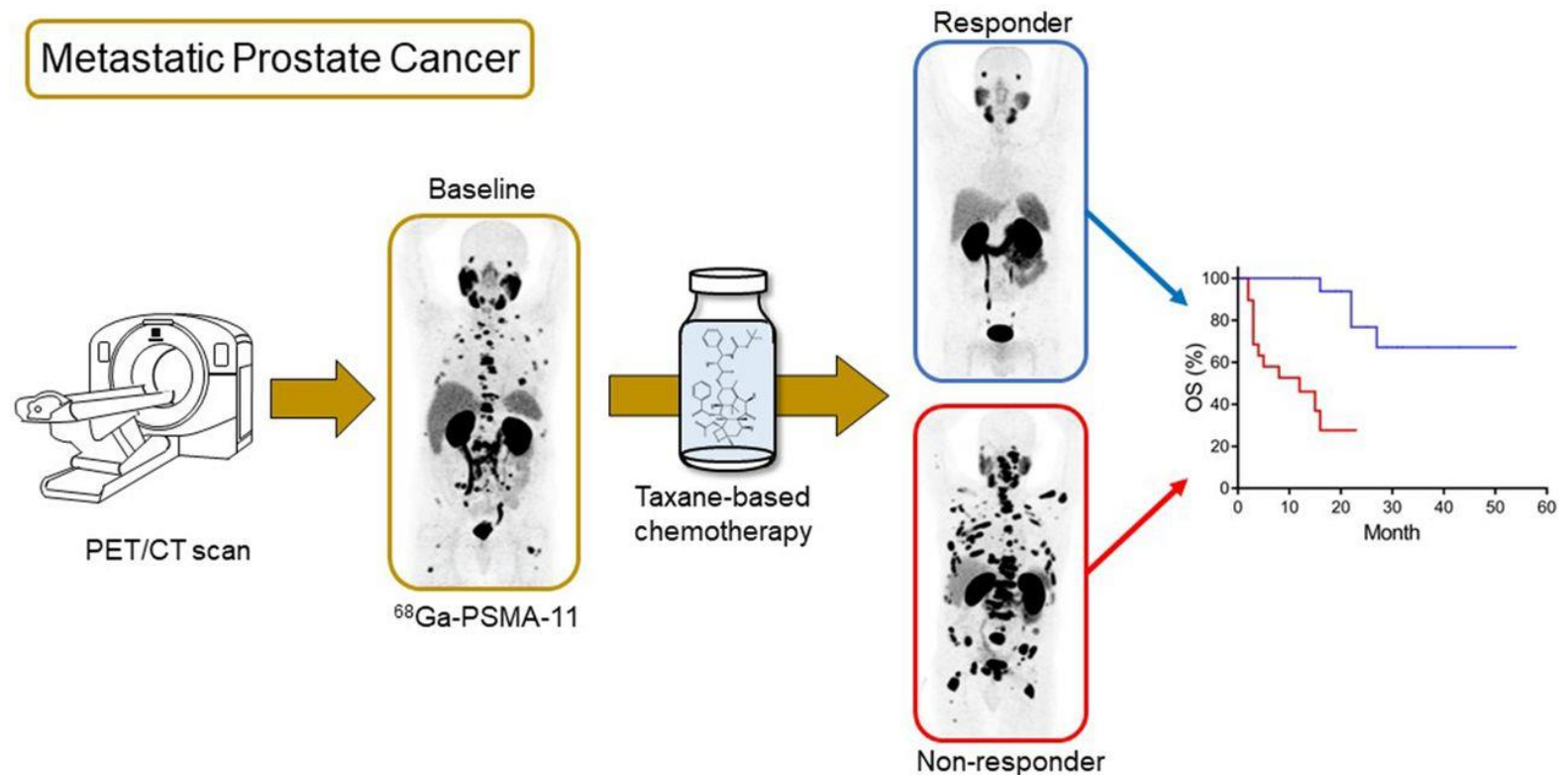
Abbreviations: N: number of patients; N° MET: number of metastasis allowed; MDT: metastasis-directed therapy; Conv: conventional; PET-Cho: PET-choline; CT: computerized tomography; BS: bone scan; MR: magnetic resonance; MDT: metastasis-directed therapy; SOC: standard of care; SABR: stereotactic ablative radiation therapy; SBRT: stereotactic body radiation therapy; ADT: androgen deprivation therapy; CRT: conventional radiation therapy; yrs: years; mo: months; P: primary; S: secondary; PFS: progression-free survival; QoL: quality of life; ADTF: freedom from ADT; PSAFS: PSA-free survival. DPFS: disease progression-free survival; HR: hazard ratio; Tox: toxicity.

^{68}Ga -PSMA PET/CT for Response Assessment and Outcome Prediction in Metastatic Prostate Cancer Patients Treated with Taxane-Based Chemotherapy

Qaid Ahmed Shagera, Carlos Artigas, Ioannis Karfis, Gabriela Critchi, Nieves Martinez Chanza, Spyridon Sideris, Alexandre Peltier, Marianne Paesmans, Thierry Gil and Patrick Flamen

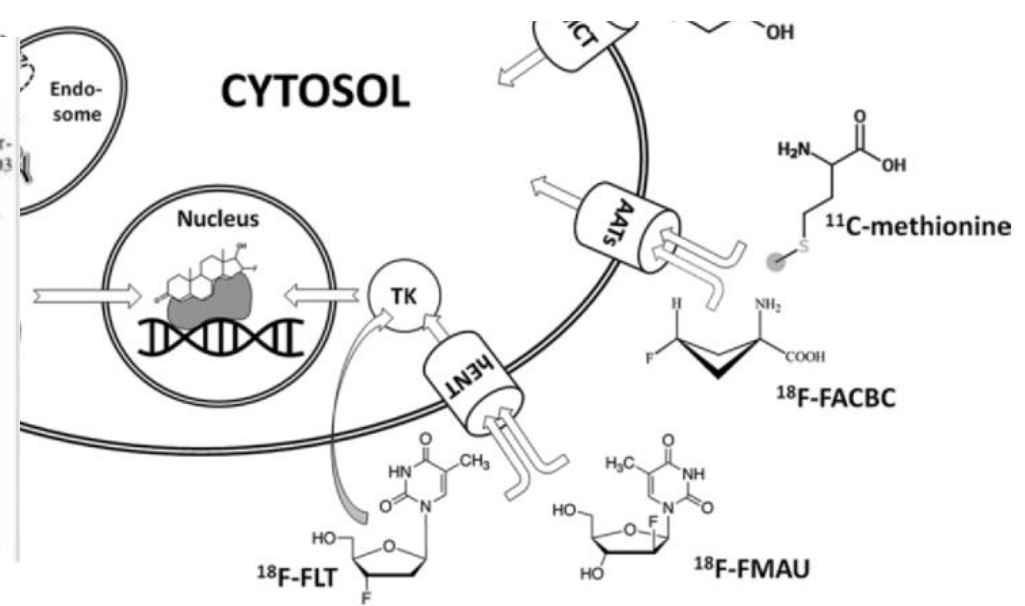
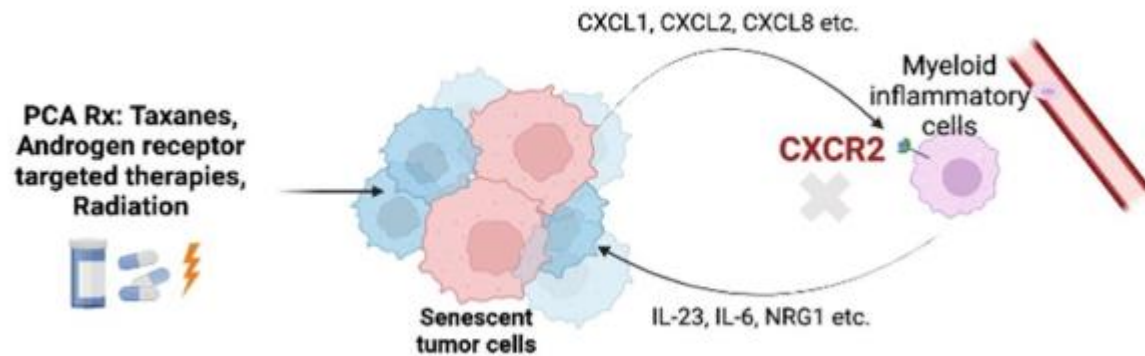
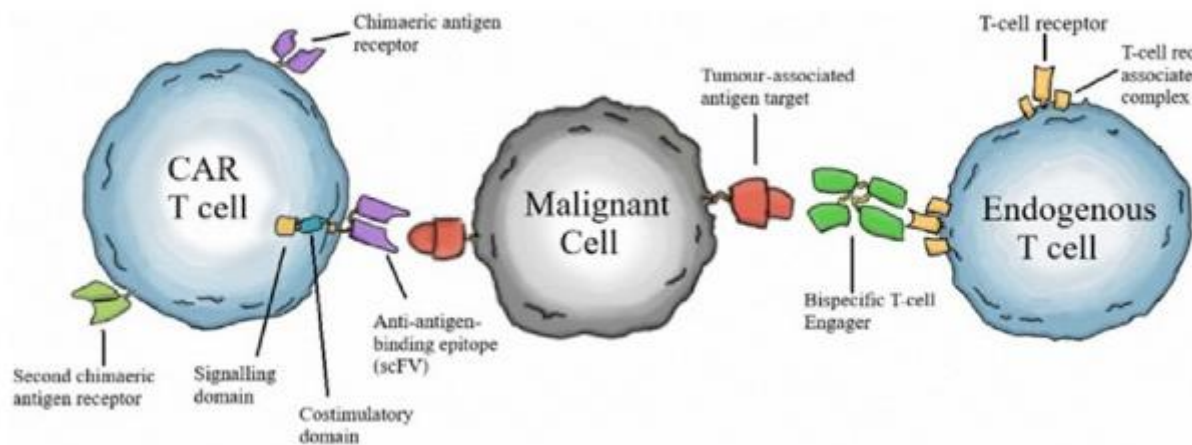
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- Longer OS for PSMA-R than for PSMA-NR (median OS not reached vs. 12 mo, respectively; hazard ratio, 0.10; 95% CI, 0.03–0.39; $P=0.001$) for the entire population.
- mCRPC subgroup differences in OS
 - median, 22 vs. 12 mo, respectively
 - hazard ratio, 0.22; 95% CI, 0.06–0.82; $P=0.023$)
 - 12-mo OS rate of 100% for PSMA-R and 52% for PSMA-NR ($P=0.011$).





Nuevas dianas para el futuro...





Conclusiones

- PET-PSMA en la estadificación puede ser el estándar en N y M a día de hoy
- Es el estándar en la recidiva en pacientes con opción radical
- Es una herramienta indispensable en la guía de terapia
- Tiene potencialidades en el seguimiento y valoración de respuesta aún carentes de suficiente evidencia