

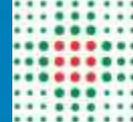
VIII EDIZIONE
NEN PRECEPTORSHIP
**LA PRATICA CLINICA NELLE
NEOPLASIE NEUROENDOCRINE**

16/17 Maggio 2019 | IEO, Istituto Europeo di Oncologia - Milano

NEN  **Preceptorship**

 **IEO**
Istituto Europeo di Oncologia





SERVIZIO SANITARIO REGIONALE
EMILIA-ROMAGNA
Azienda Unità Sanitaria Locale di Reggio Emilia
IRCCS Istituto in tecnologie avanzate e modelli assistenziali in oncologia



VIII EDIZIONE NEN PRECEPTORSHIP LA PRATICA CLINICA NELLE NEOPLASIE NEUROENDOCRINE

16/17 Maggio 2019 | IEO, Istituto Europeo di Oncologia - Milano

Approccio diagnostico-terapeutico al paziente con NET pancreatico

NEN  **Preceptorship**

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Istituto Europeo di Oncologia

Angelina Filice
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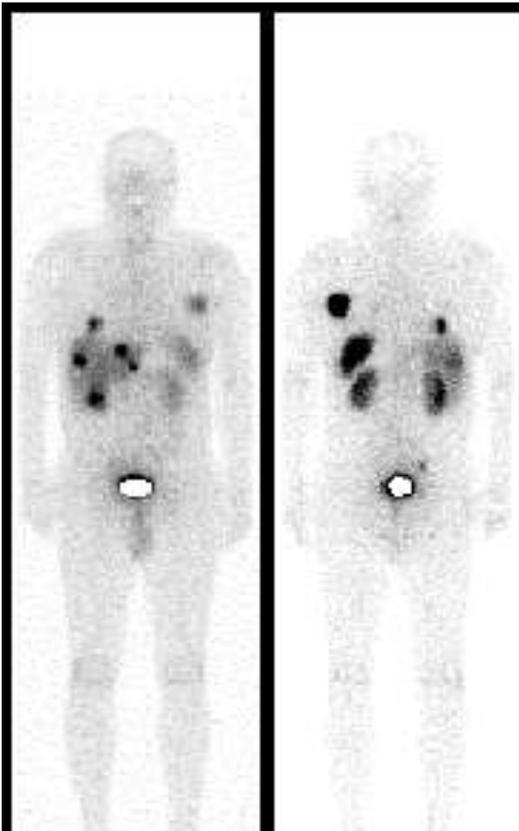
Functional imaging: quale?

Scintigrafia, SPECT, SPECT/CT

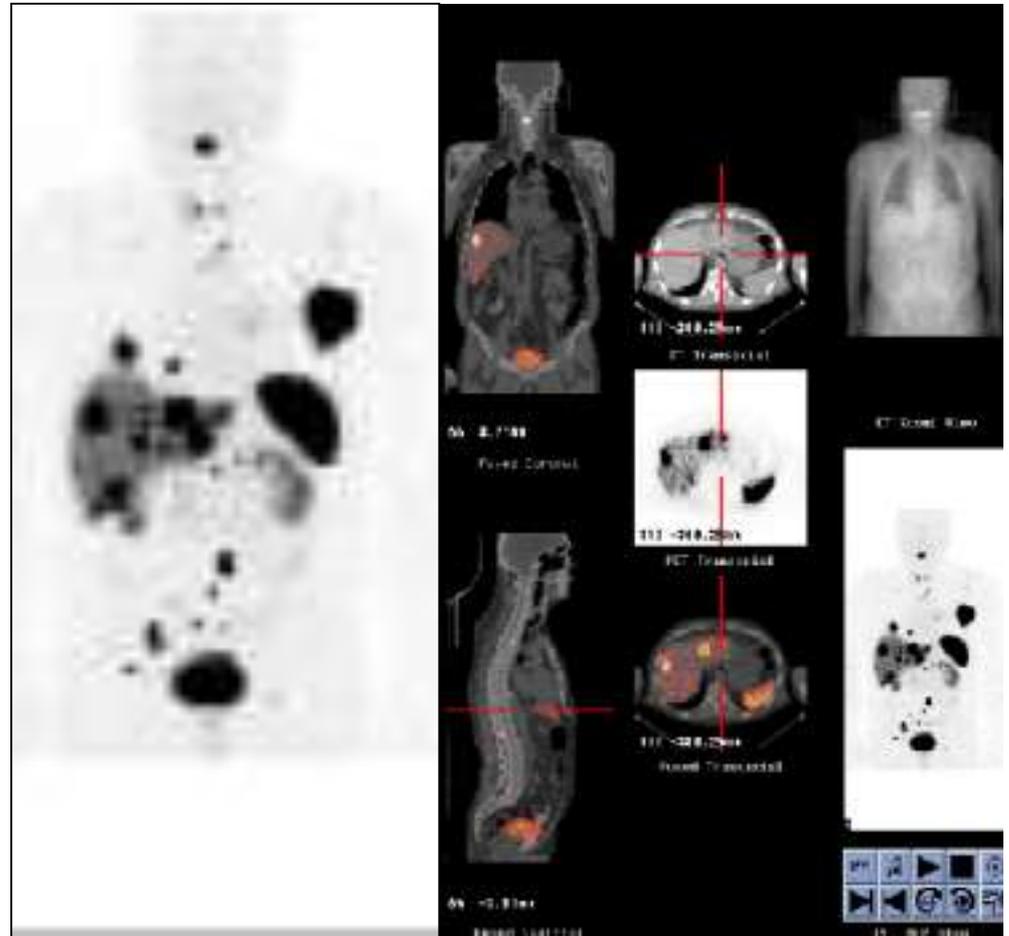
- ^{111}In -Octreoscan

PET/CT

- ^{68}Ga -DOTATOC
- ^{68}Ga -DOTANOC
- ^{68}Ga -DOTATATE

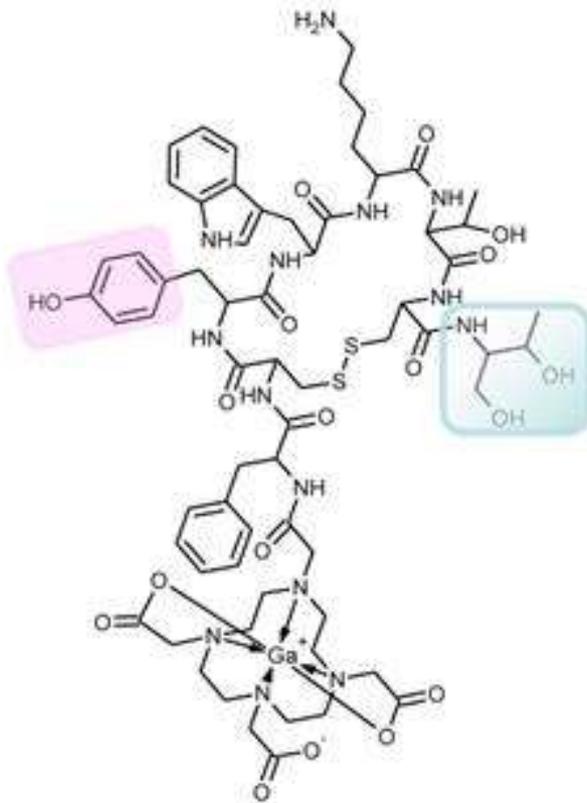


Tumore neuroendocrino del tratto gastroenteropancreatico metastatico

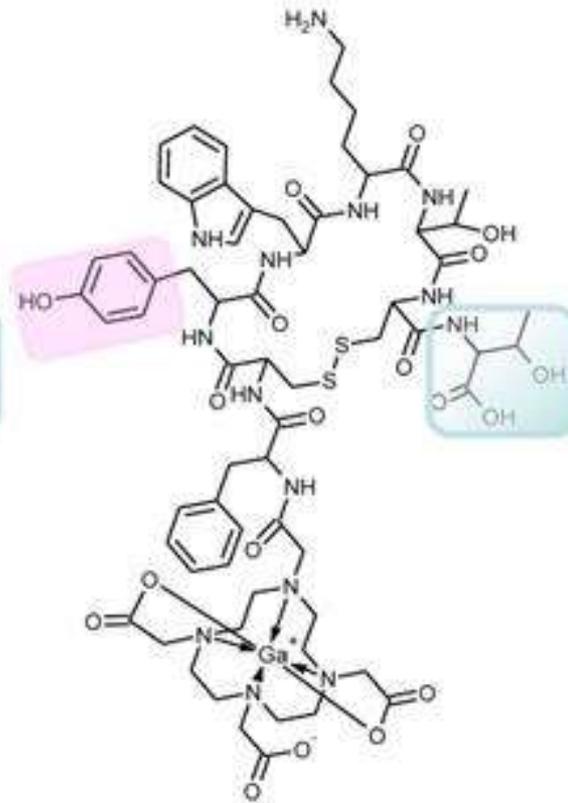


⁶⁸Ga-LABELLED SOMATOSTATIN ANALOGUES

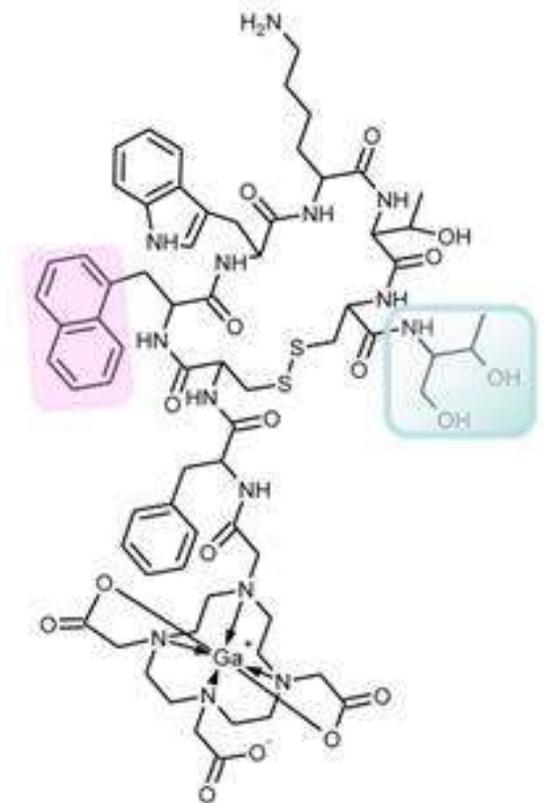
DOTATOC / TATE / NOC ...



(27) [⁶⁸Ga]Ga-DOTA-TOC



(28) [⁶⁸Ga]Ga-DOTA-TATE



(29) [⁶⁸Ga]Ga-DOTA-NOC

DOTAWHAT !?!

Current Concepts in ^{68}Ga -DOTATATE Imaging of Neuroendocrine Neoplasms: Interpretation, Biodistribution, Dosimetry, and Molecular Strategies

Lisa Bodei¹, Valentina Ambrosini², Ken Herrmann^{3,4}, and Irvin Modlin⁵

J Nucl Med 2017; 58:1718–1726

hibits substantial affinity for somatostatin receptor 3 (22). Despite these differences in receptor affinity, a clear superiority of one compound over the others has not been demonstrated. A comparison of ^{68}Ga -DOTATOC versus ^{68}Ga -DOTATATE PET/CT in the same patients yielded comparable diagnostic accuracy, despite potential advantages for ^{68}Ga -DOTATOC in the higher number of detected lesions and the higher SUV_{max} (23). However, a recent comparison



PET/CT ^{68}Ga -DOTA-peptide

L'interpretazione dei reperti a carico del pancreas richiede la massima prudenza poiché questa ghiandola può presentare un grado variabile di accumulo fisiologico/parafisiologico sia a carattere **diffuso** che **focale** e questi reperti devono essere correttamente interpretati alla luce di immagini morfologiche.



PET/CT ^{68}Ga -DOTA-peptide

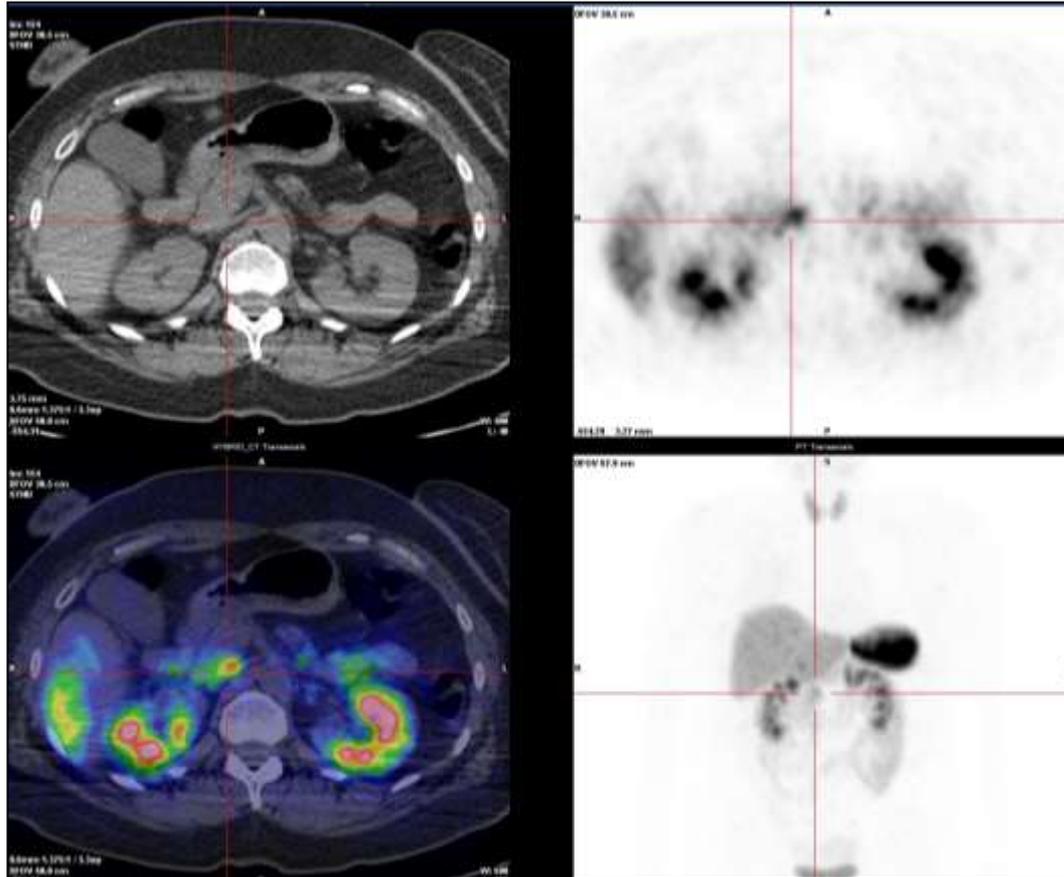
Pitfalls

- Accumulo fisiologico
- Lesioni pancreatiche benigne (iperplasia)
- Fenomeni infiammatori
- Presenza di milze accessorie

VIII EDIZIONE
NEN PRECEPTORSHIP
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NEOPLASIE NEUROENDOCRINE

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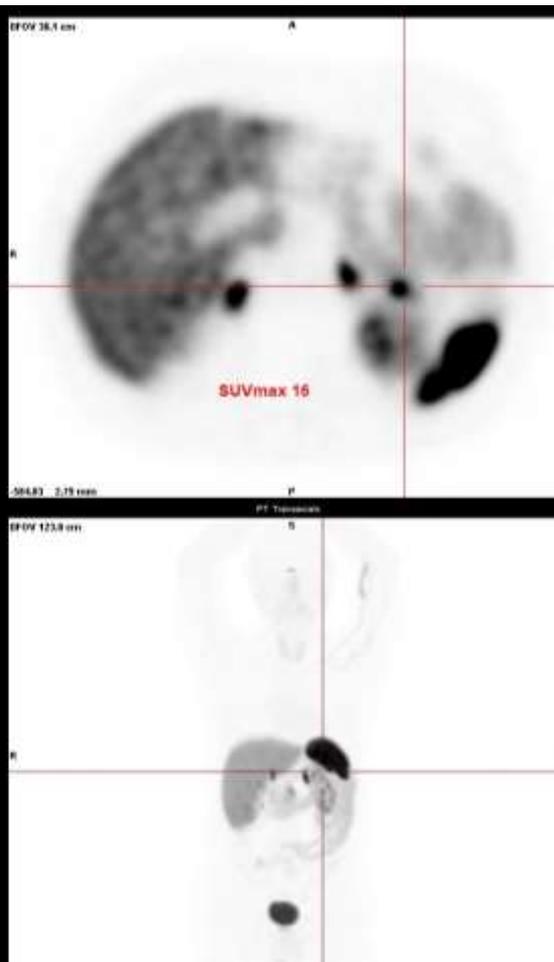
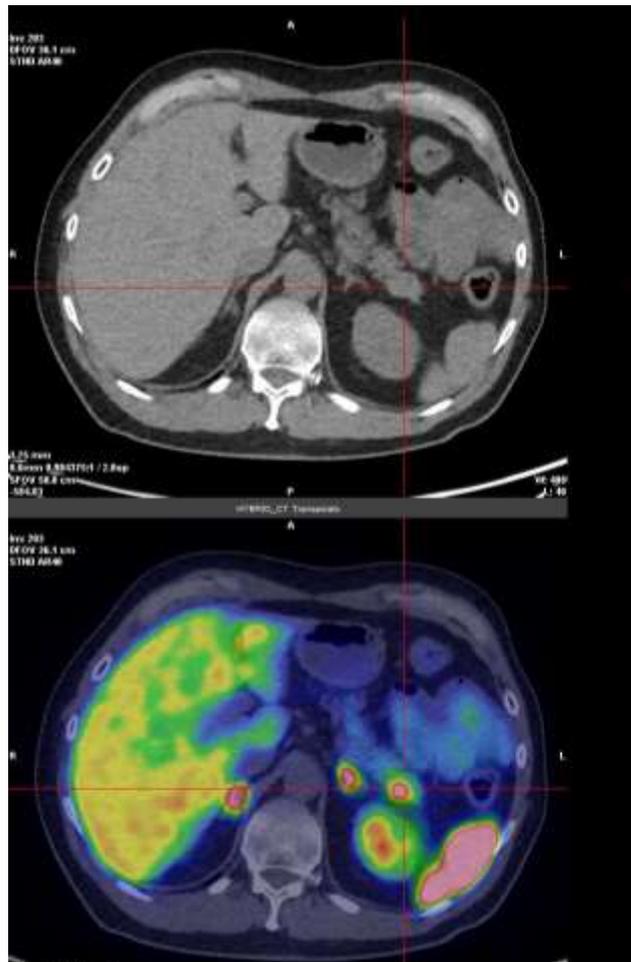
**Fisiologica captazione a livello del
processo uncinato**

verosimilmente legata alla ricca
presenza di **cellule contenenti
polipeptide pancreatico** che
sovraesprimono i ssrt

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NEOPLASIE NEUROENDOCRINE

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Diagnosi citologica
...l'insieme dei reperti è ben compatibile con una **milza accessoria intrapancreatica**.

Imaging medico-nucleare

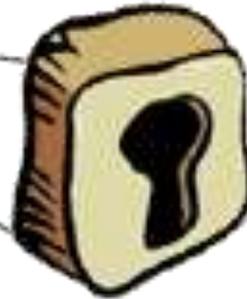
Presupposti fisiopatologici

Sito di "aggancio"
prevalente:
SSTR2



Bersaglio:

neoplasie neuroendocrine che esprimono recettori per la somatostatina



Analoghi della somatostatina

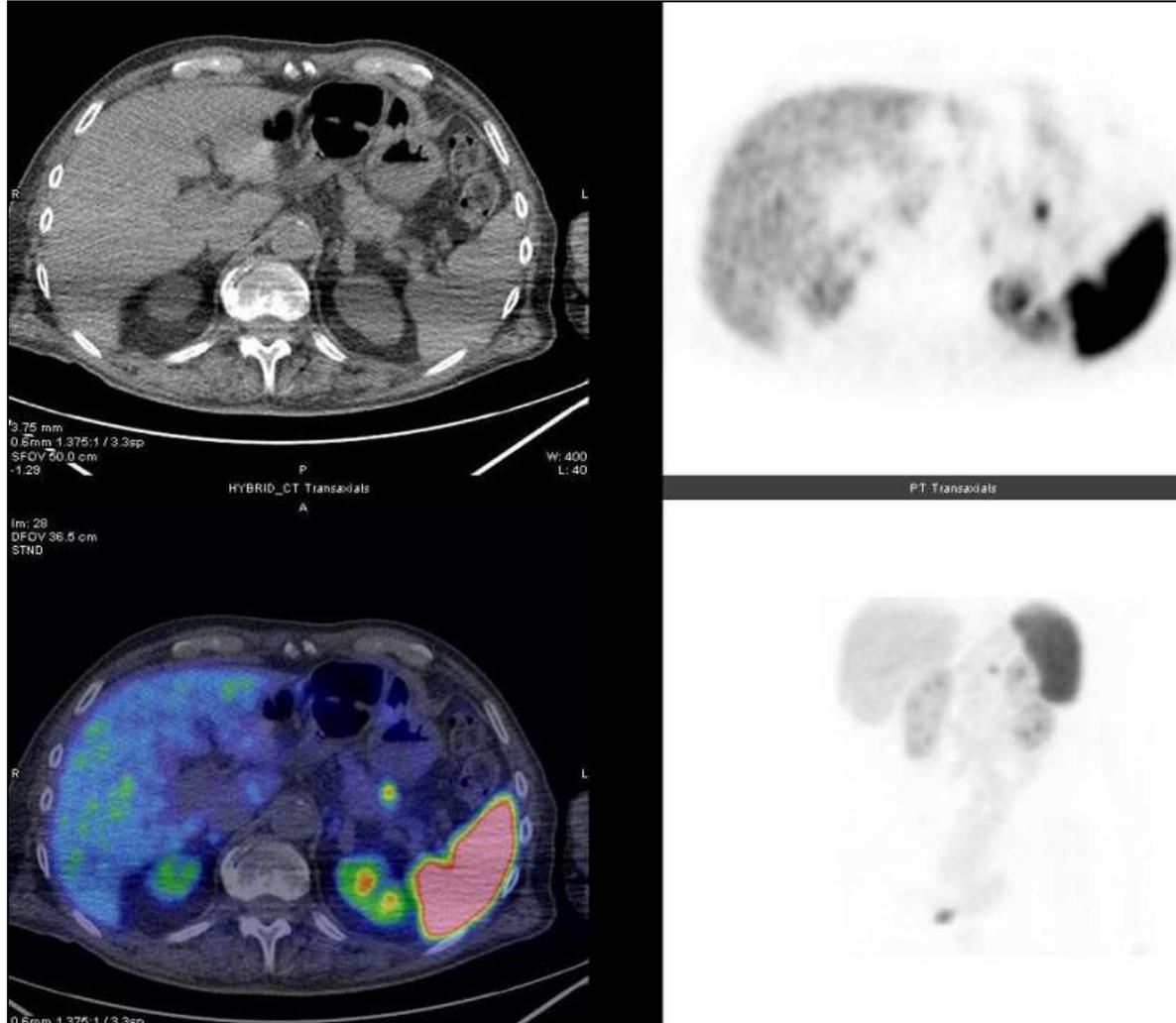
Densità di Espressione del SST-R2 nei Tumori GEP e Sensibilità dell'imaging con analoghi della somatostatina marcati

Gastrinoma	90-95%
Carcinoide	85-95%
VIP-oma	80-90%
Non-funzionanti	75-85%
Glucagonoma	70-80%
Insulinoma	50-60%

VIII EDIZIONE
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NEOPLASIE NEUROENDOCRINE

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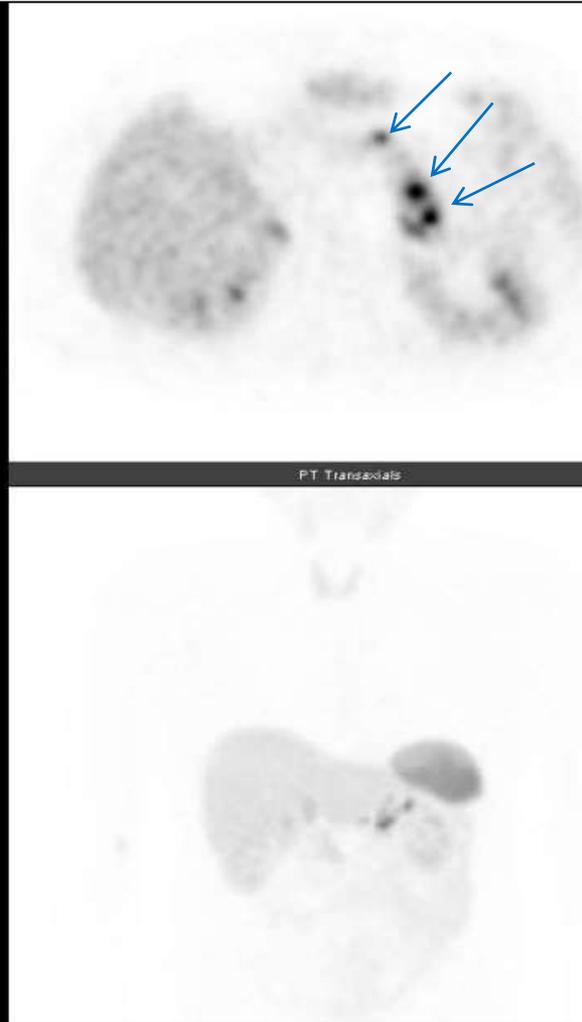
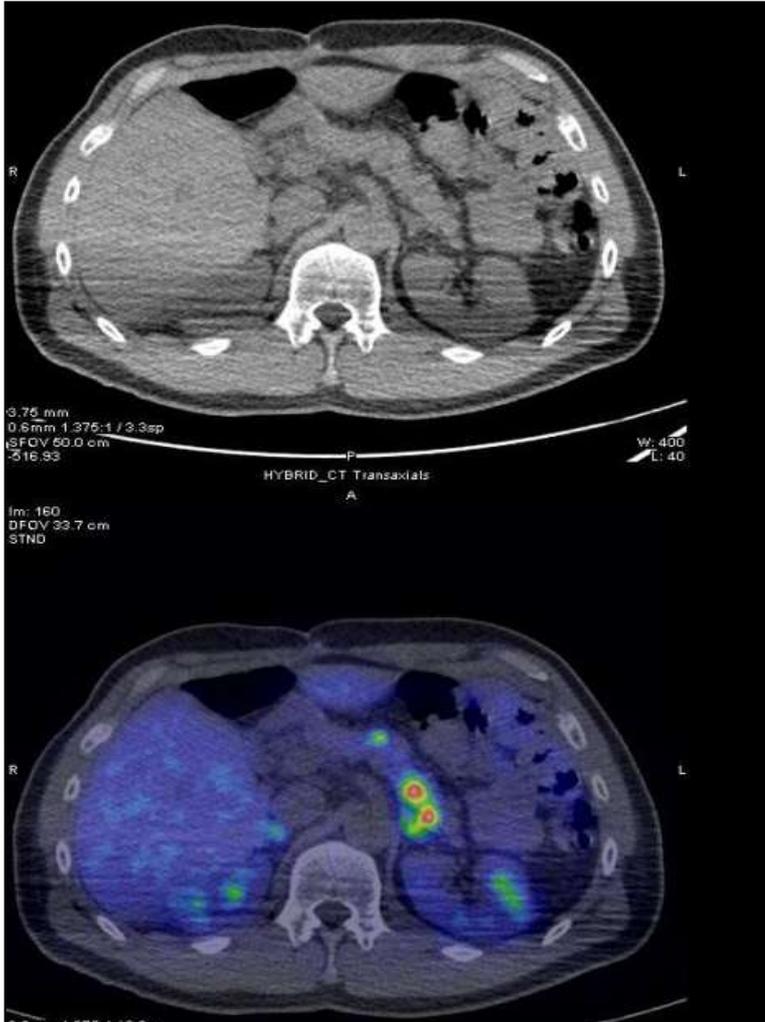
68Ga
DOTATATE
PET/CT

Insulinoma
della coda
del
pancreas

VIII EDIZIONE
NEN PRECEPTORSHIP
LA PRATICA CLINICA NELLE
NEOPLASIE NEUROENDOCRINE

NEN Preceptorship

IEO Istituto Europeo di Oncologia



68Ga
DOTATOC
PET/CT
Insulinomi
multipli
(recidiva)

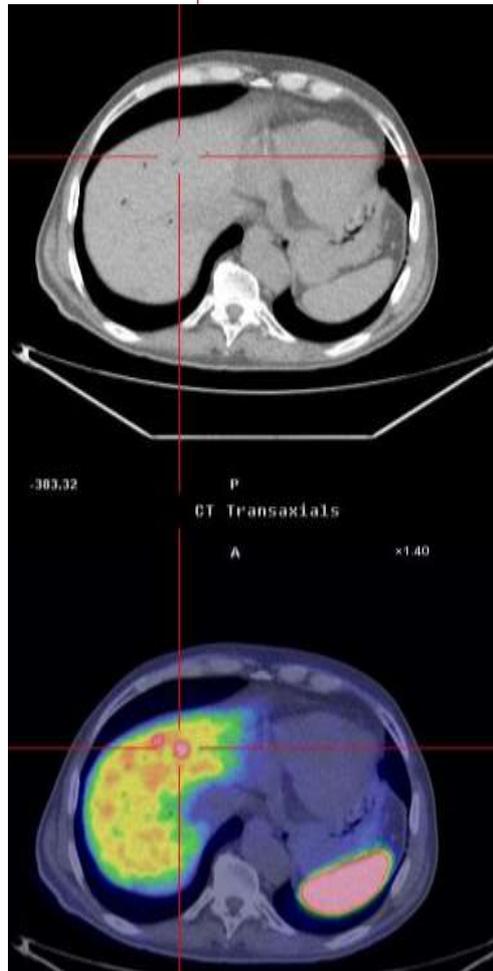
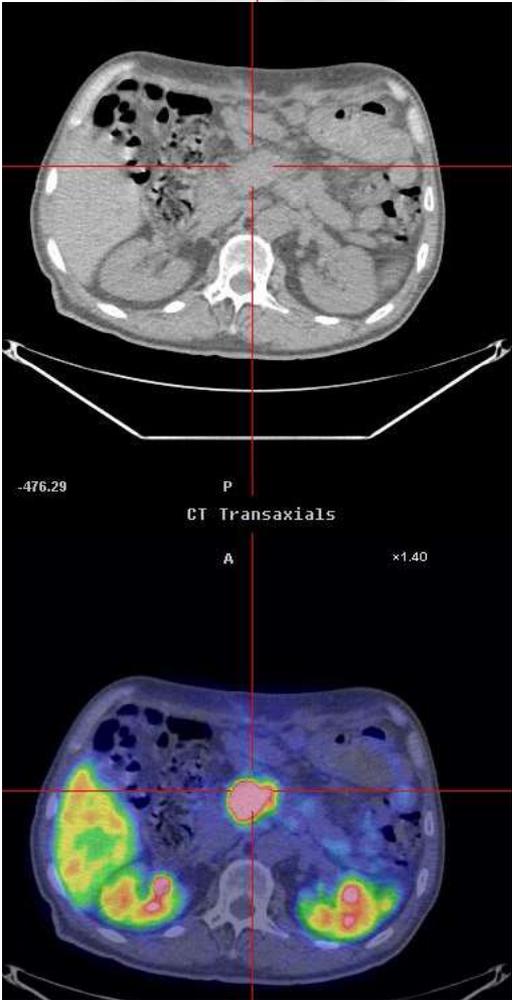
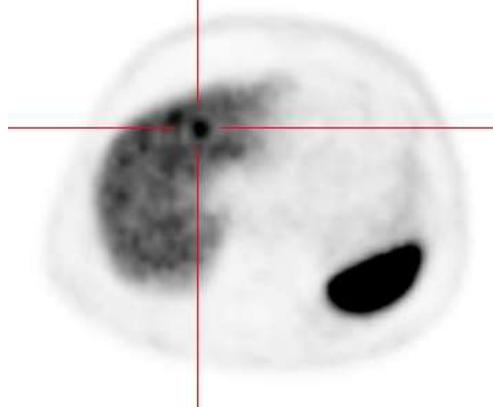
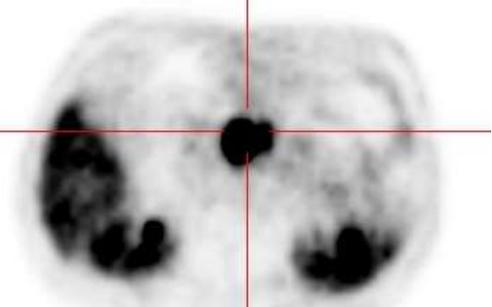
Coda
e
corpo
del
pancreas

ENETS Consensus Guidelines Update for the Management of Patients with Functional Pancreatic Neuroendocrine Tumors and Non-Functional Pancreatic Neuroendocrine Tumors

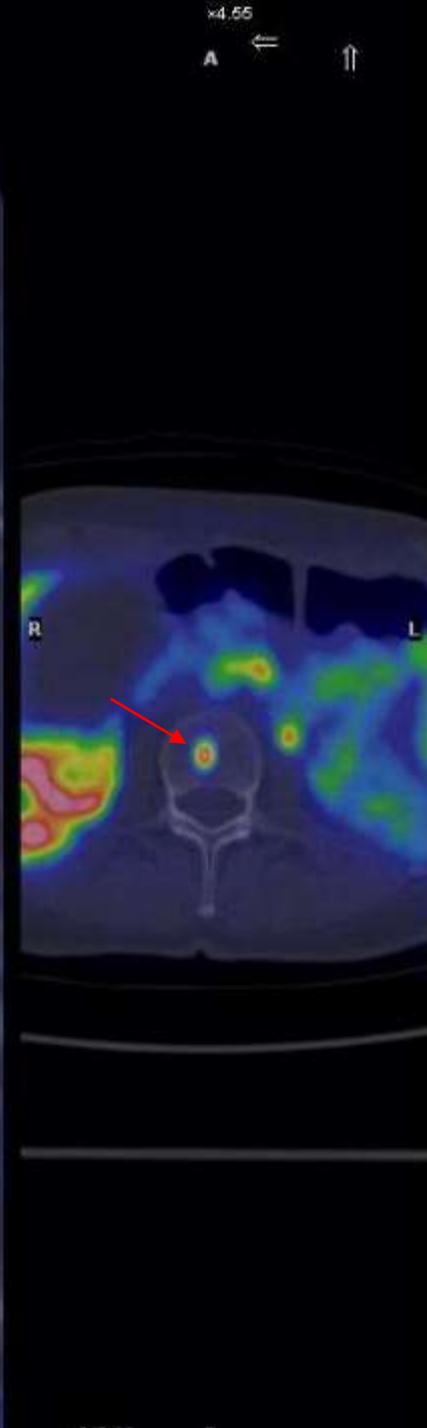
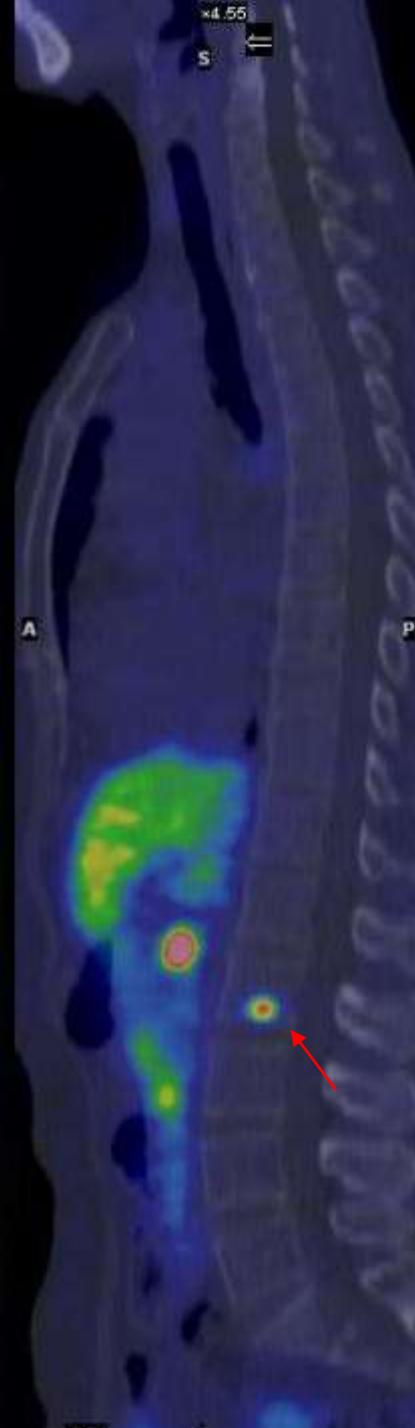
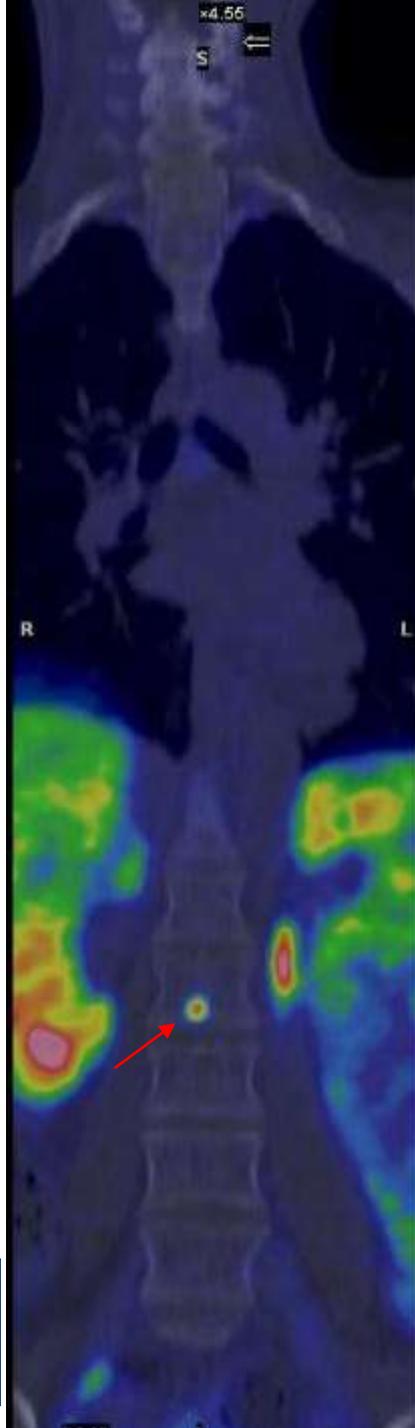
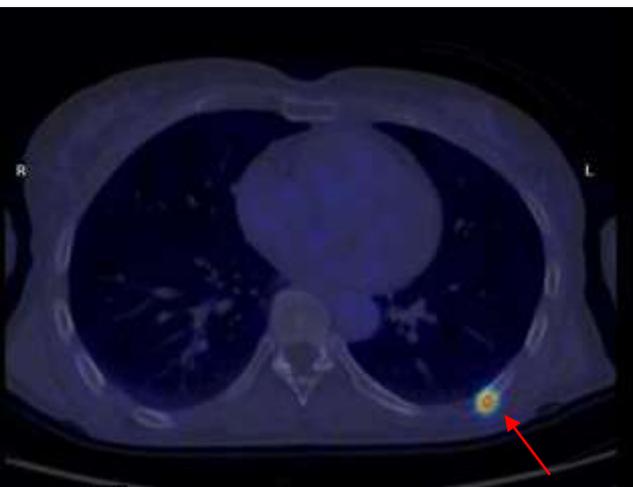
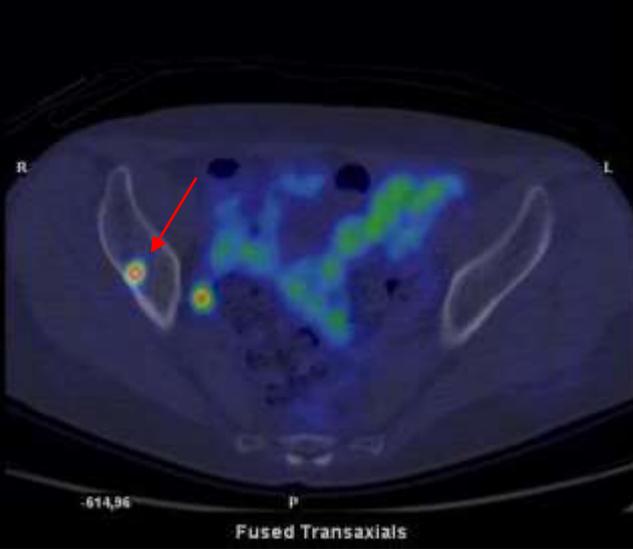
M. Falconi^a B. Eriksson^b G. Kaltsas^c D.K. Bartsch^d J. Capdevila^e M. Caplin^f
B. Kos-Kudla^g D. Kwekkeboom^h G. Rindiⁱ G. Klöppel^j N. Reed^k R. Kianmanesh^l
R.T. Jensen^m all other Vienna Consensus Conference participants

insulinomas, in which case the sensitivity was only 25% [90]. The consequence of these findings is that PET/CT is now the method of choice to fully stage and localize the extent of disease in patients with non-insulinoma P-NETs [83, 91]. ⁶⁸Ga-labeled somatostatin analogues have been shown to change the management (surgical, medical, staging) in 20–55% of all patients [87, 88, 92, 93] and, therefore, they should generally be used in patients with non-insulinoma P-NETs.

^{68}Ga -DOTATOC PET



Carcinoma neuroendocrino del pancreas con metastasi epatiche



**Metastasi scheletriche
da NET pancreatico**

^{111}In -Octreoscan and ^{68}Ga -DOTA peptide PET/CT EANM guidelines

- **Primary tumor localization and staging**
- **Restaging (detection of residual, recurrent or progressive disease)**
- **SSTR status evaluation (patients with high positivity are more likely to respond to octreotide therapy)**
- **Response to therapy monitoring**
- **Selection of patients for peptide receptor radionuclide therapy (PRRT)**

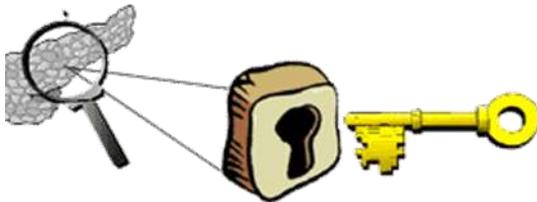
*Bombardieri E Eur J Nucl Med 2010
Virgolini I Eur J Nucl Med 2010*

TERAGNOSTICA



- L'idea che sta dietro al concetto di teranostica è quella di poter usare la **stessa combinazione di agenti** per identificare (**diagnosi**) e trattare (**terapia**) un tessuto target.
- Il termine è stato coniato per la **prima volta** nel **1998** da **John Funkhouser** e riferito al matching tra INR e terapia anticoagulate.
- Il concetto di usare lo stesso agente per la diagnostica e per la terapia è ampiamente usato in medicina.

TERAGNOSTICA: Tumori Neuroendocrini



Diagnostica

DOTATOC/TATE



Terapia

TERAGNOSTICA: Tumori Neuroendocrini

Scintigrafia in corso di trattamento radiorecettoriale con ^{177}Lu -DOTATOC

168 Gy ^{177}Lu
93 Gy ^{90}Y



I trattamento valutazione
dosimetrica ^{177}Lu -DOTATOC



III trattamento
 ^{177}Lu -DOTATOC



VI trattamento
 ^{177}Lu -DOTATOC

B.M.
54 aa

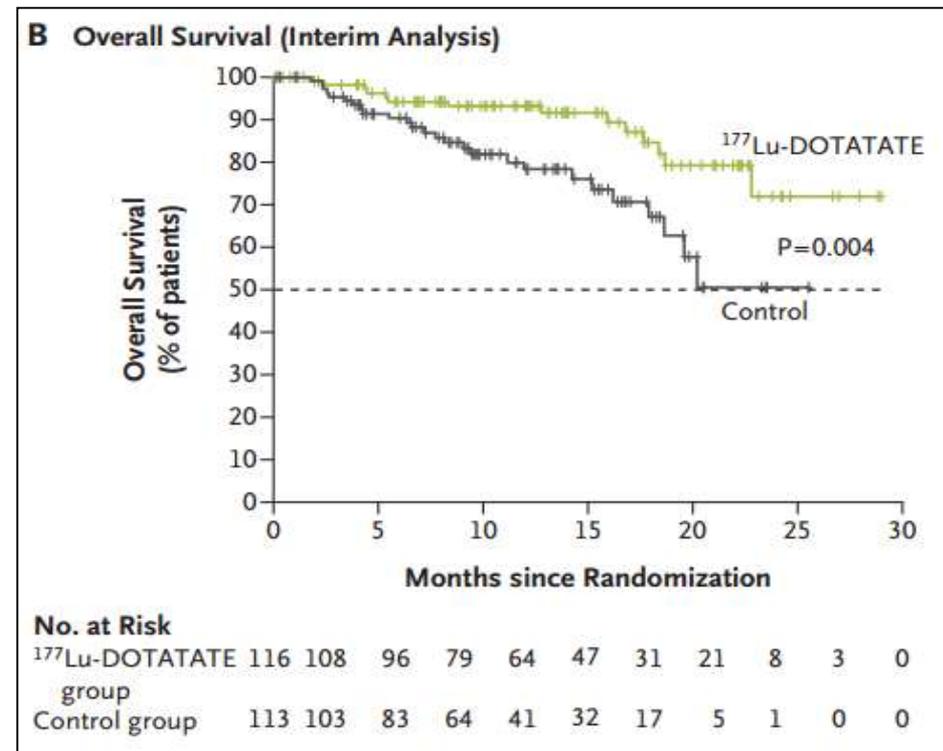
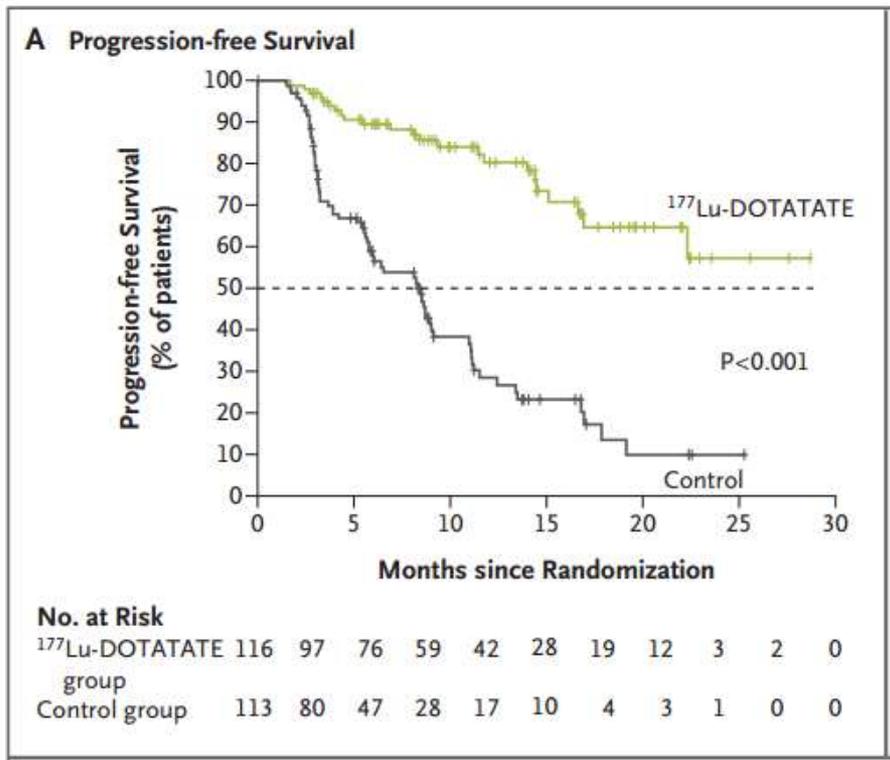
Peptide Receptor Radionuclide Therapy (PRRT)

Author	Year	Radiopharmaceutical	N° Pts.	Primary NET	Response (%)				
					CR	PR	MR	SD	PD
Waldherr	2001	90Y-DOTATOC	41	GEP+lung	2	22	12	49	15
Waldherr	2002	90Y-DOTATOC	39	GEP+lung	5	18	-	65	11
Valkema	2006	90Y-DOTATOC	58	GEP	0	9	12	61	19
Kwekkeboom	2008	177Lu-DOTATATE	310	GEP	2	28	16	35	20
Bodei	2011	177Lu-DOTATATE	51	GEP+lung	2	27	26	27	18
Filice	2012	90Y/177Lu-DOTATOC	59	GEP+lung	2	40	-	40	18
Vinjamuri	2013	90Y-DOTATOC	57	GEP+lung	-	25	-	47	28
Mariniello	2015	90Y/177Lu DOTATOC	117	Lung	0	13	13	41	33

ORIGINAL ARTICLE

Phase 3 Trial of ¹⁷⁷Lu-Dotatate for Midgut Neuroendocrine Tumors

Midgut NET, progressive under Octreotide LAR



➔ 4 administrations of 7.4 GBq of ¹⁷⁷Lu-Dotatate every 8 weeks + SSAs (symptoms control)

➔ Octreotide LAR (high dose - 60mg every 4 weeks¹)

Interdisciplinary Discussion

What treatment?

Before NETTER1

Somatostatin Analogs?
Biological Pharmaceutical?
Chemotherapy?

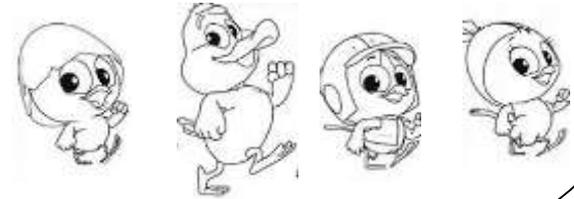


PRRT?



After NETTER1

Somatostatin Analogs?
Biological Pharmaceutical?
Chemotherapy?
PRRT?



- European Medicines Agency - EMA - Food and Drug Administration - FDA



AGENZIA ITALIANA DEL FARMACO

DETERMINA 11 marzo 2019

Indicazione terapeutica:

Tumori neuroendocrini gastroenteropancreatici (GEPNET)

Ben differenziati (G1 e G2)

In progressione

Non operabili o metastatici

Positivi ai recettori per la somatostatina



In considerazione:

- del fatto che le **principali linee guida internazionali** mettono in principale rilievo il **grado di differenziazione neoplastica** e l'**indice di proliferazione** (Ki67<20%) piuttosto che la specifica localizzazione del tumore primitivo.
- dei dati derivati dallo **studio a supporto ERASMUS (fase I-II)** su tutti i GEP-NET.

Long-Term Efficacy, Survival, and Safety of [¹⁷⁷Lu-DOTA⁰,Tyr³]octreotate in Patients with Gastroenteropancreatic and Bronchial Neuroendocrine Tumors

Tessa Brabander¹, Wouter A. van der Zwan¹, Jaap J.M. Teunissen¹, Boen L.R. Kam¹,
Richard A. Feelders², Wouter W. de Herder², Casper H.J. van Eijck³, Gaston J.H. Franssen³,
Eric P. Krenning¹, and Dik J. Kwekkeboom^{1,†}



Studio Erasmus di fase I/II

Lo studio aveva arruolato **1214 pazienti** di cui 811 di nazionalità olandese mentre i restanti provenivano da vari Paesi europei e non-europei.

L'**analisi di efficacia** è stata condotta sui **443 pazienti** trattati con dosi ≥ 600 mCi di 177-Lu-DOTATATE.

Le sedi del tumore primario più rappresentate erano: la **sede Pancreatica** con **133** pazienti e le **sedi del Midgut** (intestino tenue, appendice e colon dx) con **181** pazienti.

La sopravvivenza globale (OS) mediana di questi 443 Pazienti è stata di 63 mesi (95% CI, 55-72 mesi) mentre la sopravvivenza libera da progressione (PFS) mediana è stata di 29 mesi (95% CI, 26-33 mesi).

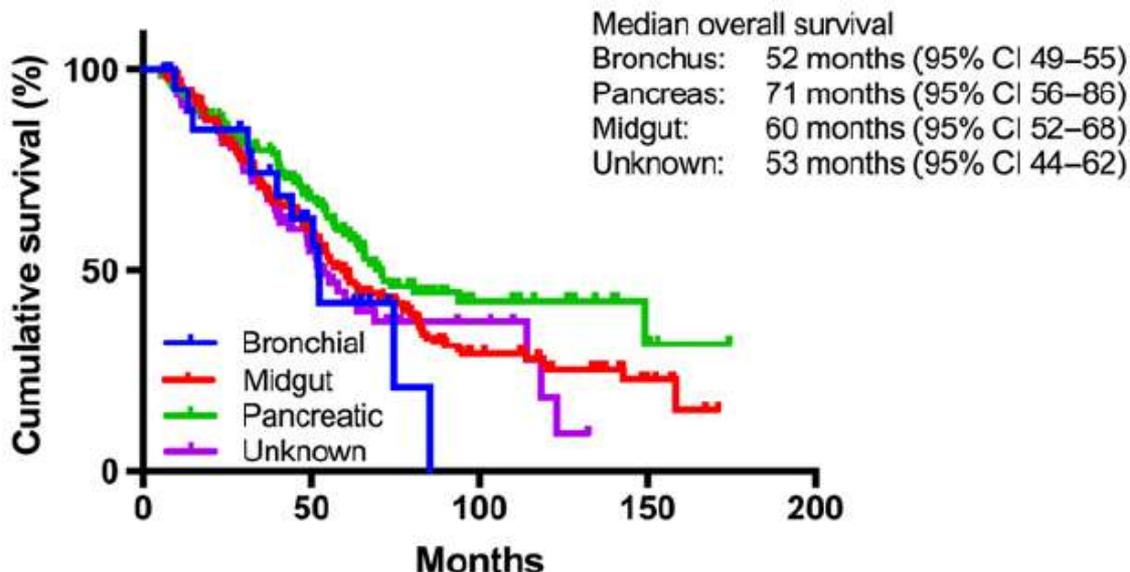
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I pazienti con sede tumorale pancreatica hanno avuto una **maggiore sopravvivenza globale (OS)** 71 mesi (95% CI, 56-86 mesi).

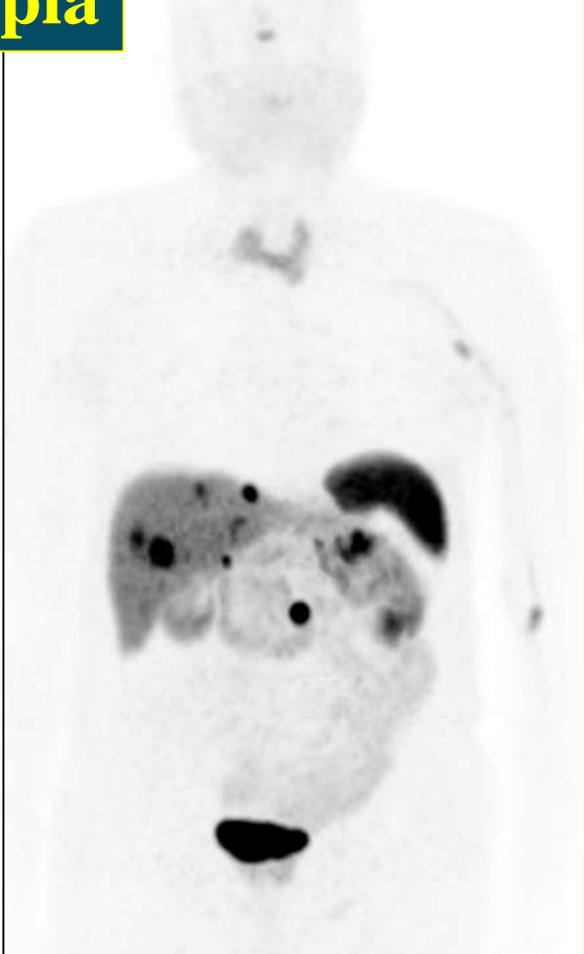
Figure 2. Median OS in 419 NET patients treated with ¹⁷⁷Lu-DOTATATE according to location of the primary tumor. Not shown are patients with primary tumor of the hindgut (*n* = 12) and other foregut (*n* = 12) due to the small number of patients.



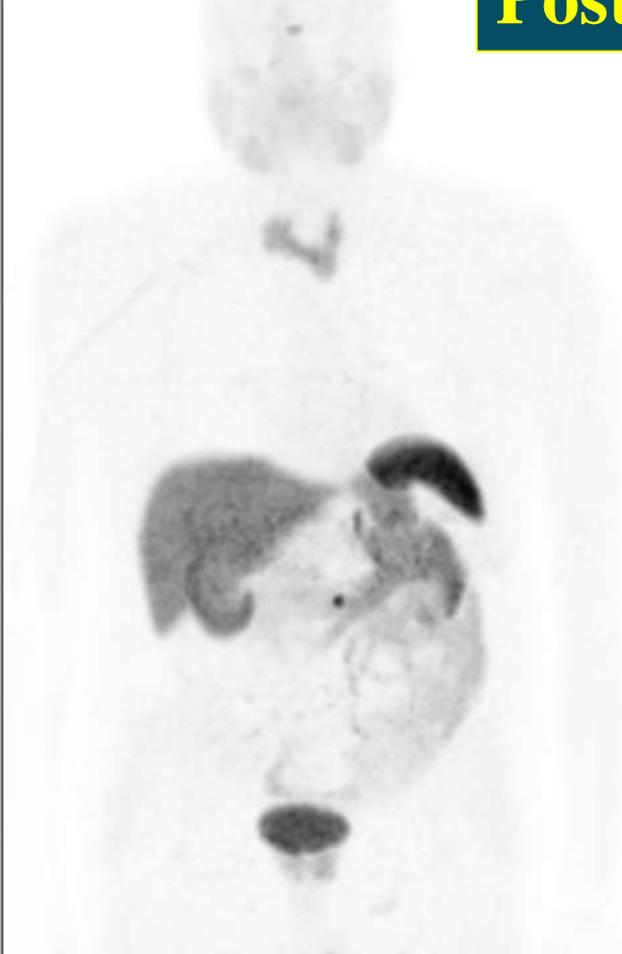
No at risk	0	50	100	150	200
Bronchus	23	10	0	0	0
Midgut	181	92	28	7	7
Pancreas	133	71	17	4	4
Unknown	82	31	7	0	0

^{68}Ga -DOTATATE PET/CT

Pre-terapia



Post-terapia



M, 73 y: NET pancreatico con metastasi epatiche
2 cicli di ^{90}Y e 4 cicli di ^{177}Lu . PR

Considerazioni

I dati disponibili sono a favore della PRRT come modalità di trattamento nei panNET.

Sono attualmente disponibili diverse altre terapie per panNET avanzato.

Stabilire la **corretta sequenza e combinazione** di PRRT con le altre terapie disponibili sarà la grande sfida per il futuro della gestione delle panNET.

Considerazioni

- caratteristiche del tumore
- carico della malattia
- espressione recettoriale
- disponibilità di PRRT
- preferenze dei pazienti
- valutazione della tossicità a lungo termine



Terapia radiorecettoriale
con ^{177}Lu -DOTATATE

Terapia radiorecettoriale
con Lutathera

13 anni

I trattamento a RE nel 2006

I trattamento a RE il 13 maggio 2019





HHS Public Access

Author manuscript

J Nucl Med. Author manuscript; available in PMC 2017 January 12.

Published in final edited form as:

J Nucl Med. 2016 May ; 57(5): 715–720. doi:10.2967/jnumed.115.167445.

Glucagon-Like Peptide-1 Receptor PET/CT with ⁶⁸Ga-NOTA-Exendin-4 for Detecting Localized Insulinoma: A Prospective Cohort Study

Yaping Luo¹, Qingqing Pan¹, Shaobo Yao¹, Miao Yu², Wenming Wu³, Huadan Xue⁴, Dale O. Kiesewetter⁵, Zhaohui Zhu¹, Fang Li¹, Yupei Zhao³, and Xiaoyuan Chen⁵

43 pazienti

In recent years, a new receptor-targeted imaging technique, **glucagon-like peptide-1 receptor (GLP-1R)** imaging, for detecting insulinoma has been established. GLP-1R is **expressed on benign insulinoma cell surfaces** with very high incidence (>90%) and density (8,133 dpm/mg of tissue).

Contents lists available at [ScienceDirect](#)

Seminars in Oncology

journal homepage: www.elsevier.com/locate/seminoncol

Peptide receptor radionuclide therapy for patients with advanced pancreatic neuroendocrine tumors

John Ramage^a, Boris G. Naraev^b, Thorvardur R. Halfdanarson^{c,*}

^a Kings Health Partners Neuroendocrine Centre, London, UK

^b Banner MD Anderson Cancer Center, Gilbert, AZ, USA

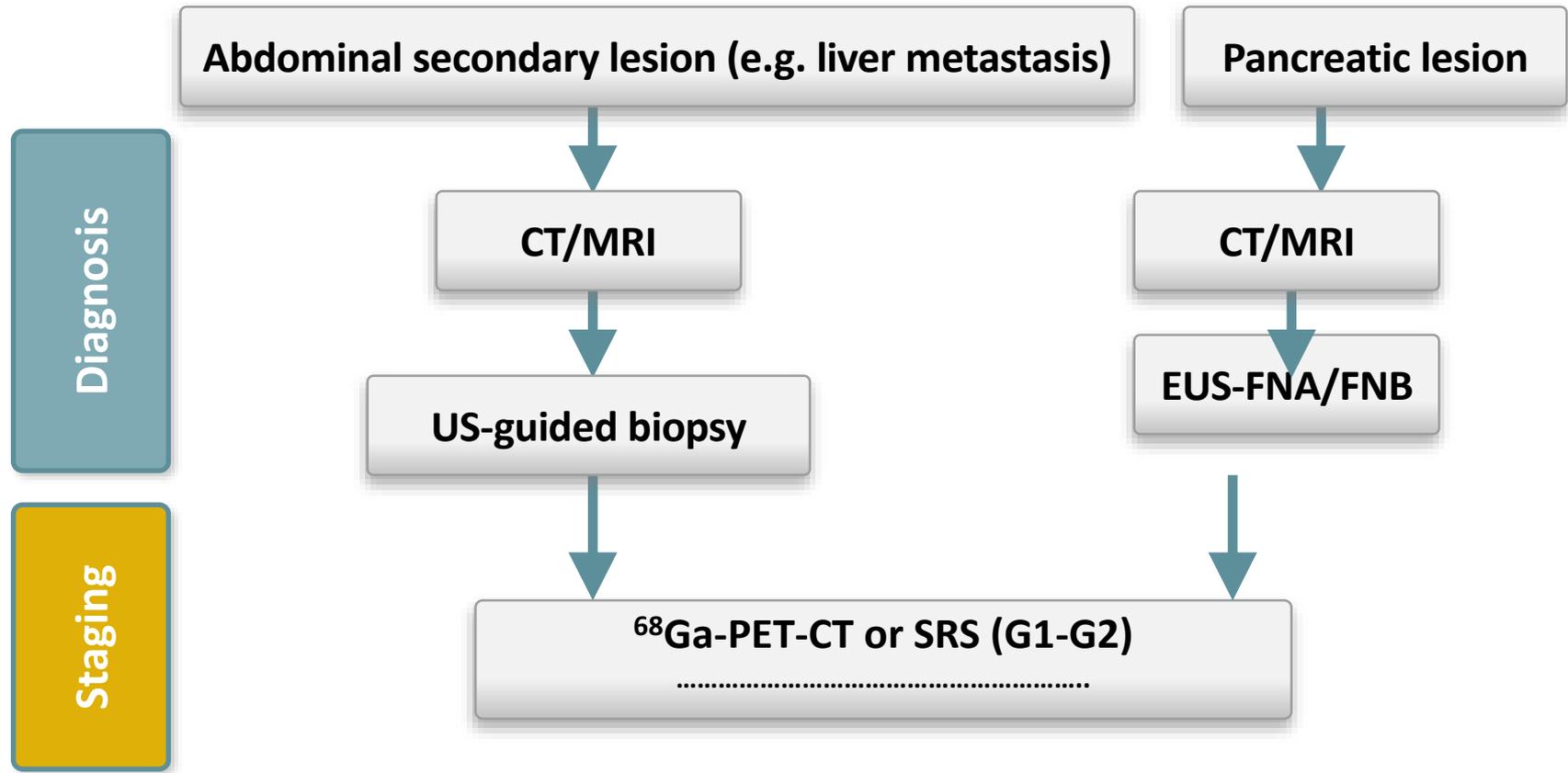
^c Mayo Clinic Cancer Center, Rochester, MN, USA

Among these studies, the median disease control rate (DCR) was 83% (range, 50%–94%) and the median objective response rate (ORR) was 58% (range, 13%–73%).

Reported median PFS for the overall panNET populations in each study ranged from 25 to 34 months, and the median OS ranged from 42 to 71 months.

Italian Association of Clinical Endocrinologists (AME) position statement: a stepwise clinical approach to the diagnosis of gastroenteropancreatic neuroendocrine neoplasms

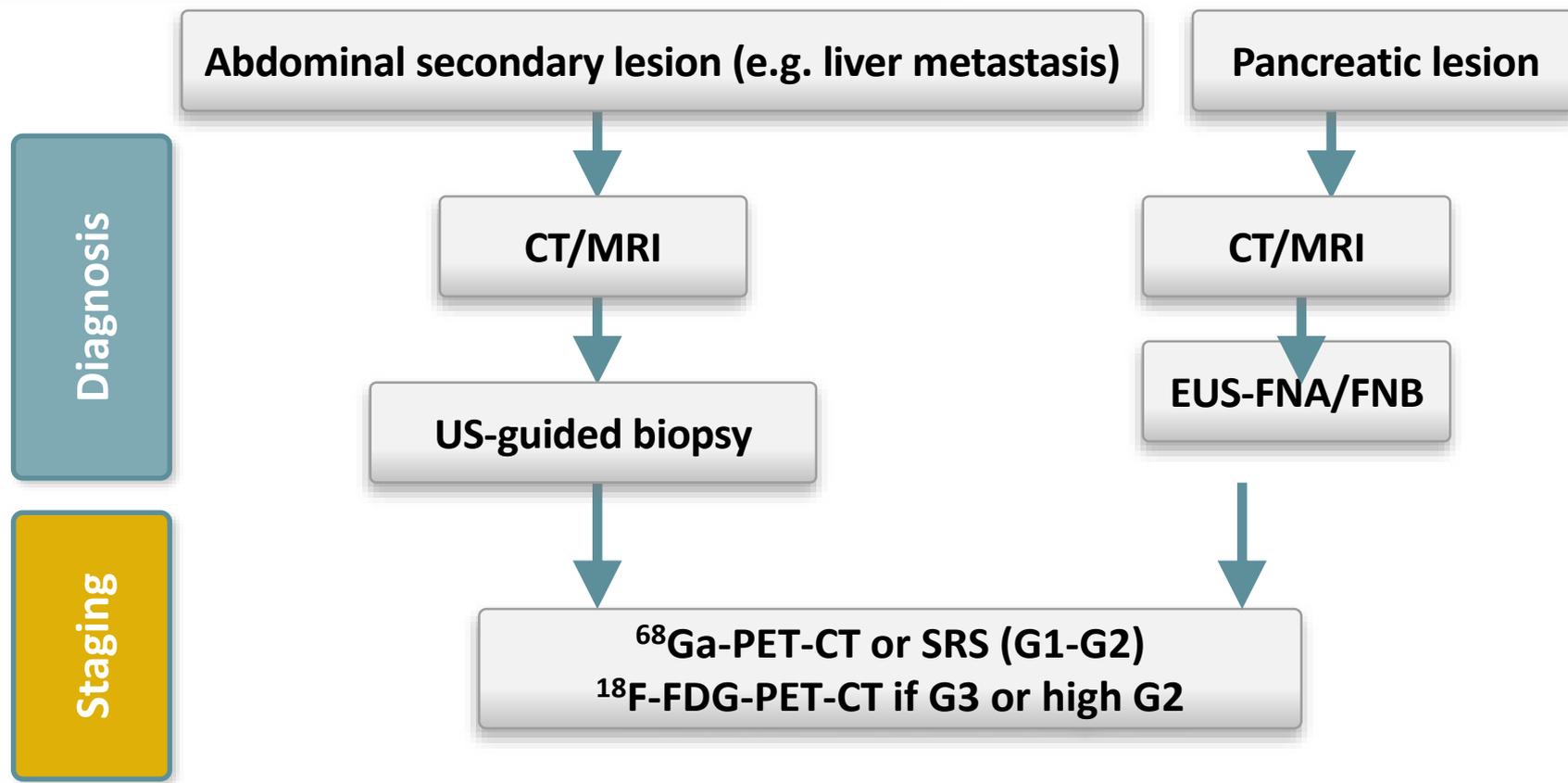
Franco Grimaldi · Nicola Fazio · Roberto Attanasio · Andrea Frasoldati · Enrico Papini · Francesco Angelini · Roberto Baldelli · Debora Berretti · Sara Bianchetti · Giancarlo Bizzarri · Marco Caputo · Roberto Castello · Nadia Cremonini · Anna Crescenzi · Maria Vittoria Davi · Angela Valentina D'Elia · Antongiulio Faggiano · Stefano Pizzolitto · Annibale Versari · Michele Zini · Guido Rindi · Kjell Öberg



Diagnostic flow-chart for GEP-NEN suspected at morphological imaging

Italian Association of Clinical Endocrinologists (AME) position statement: a stepwise clinical approach to the diagnosis of gastroenteropancreatic neuroendocrine neoplasms

Franco Grimaldi · Nicola Fazio · Roberto Attanasio · Andrea Frasoldati · Enrico Papini · Francesco Angelini · Roberto Baldelli · Debora Berretti · Sara Bianchetti · Giancarlo Bizzarri · Marco Caputo · Roberto Castello · Nadia Cremonini · Anna Crescenzi · Maria Vittoria Davi · Angela Valentina D'Elia · Antongiulio Faggiano · Stefano Pizzolitto · Annibale Versari · Michele Zini · Guido Rindi · Kjell Öberg



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PET/CT ⁶⁸Ga-DOTA-peptide

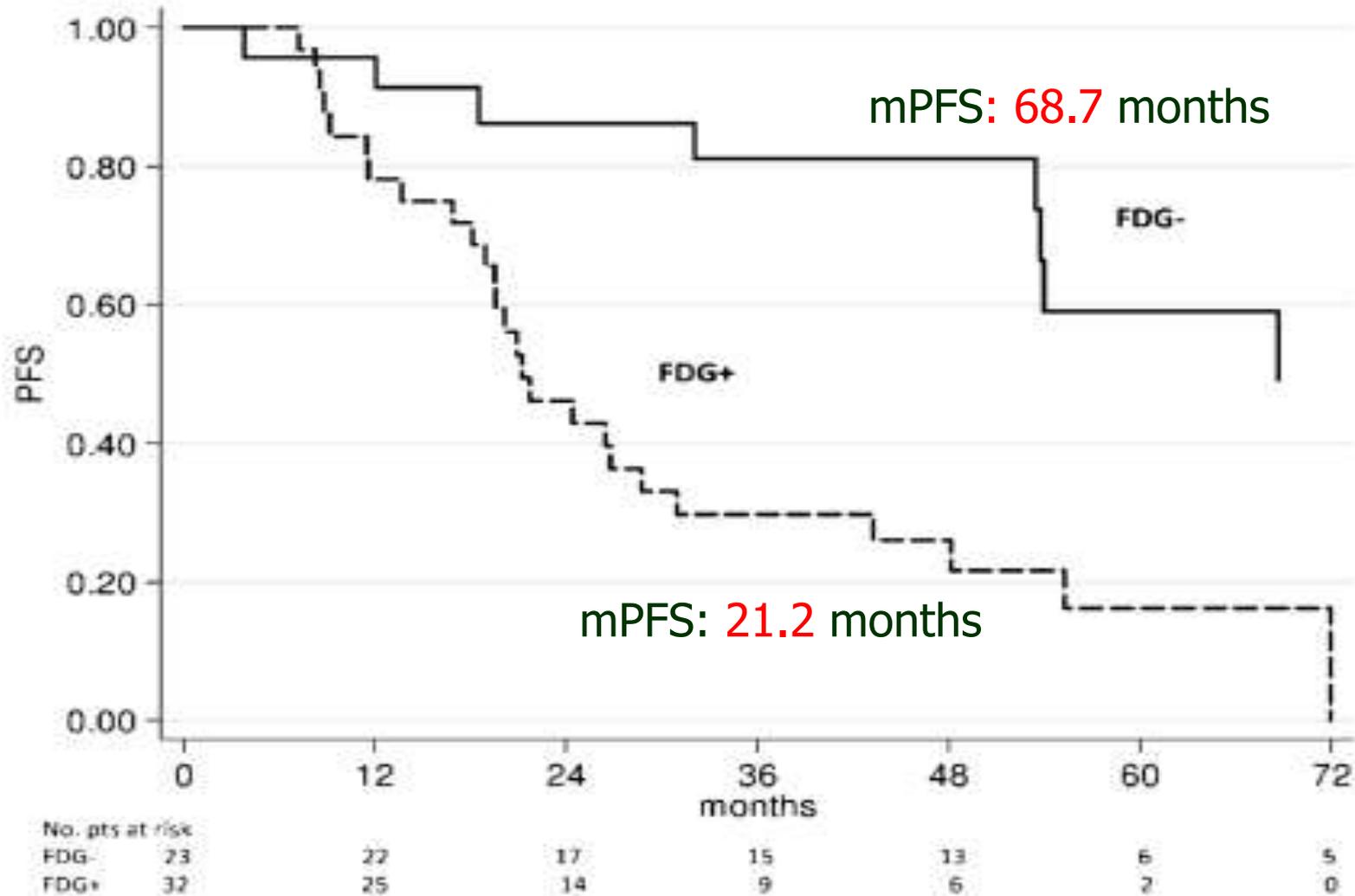
...less uptake occurs on SSTR imaging of G3 tumors, and for this reason G3 NEC are generally imaged with 18F-FDG PET.

Use of 18F-FDG PET has also been proposed alongside Gallium-68 SSTR imaging, in G2 NET with a Ki-67 >10%, for its role in identifying patients with tumors that are more likely to progress.

Long-term follow-up and role of FDG PET in advanced pancreatic neuroendocrine patients treated with ¹⁷⁷Lu-D OTATATE

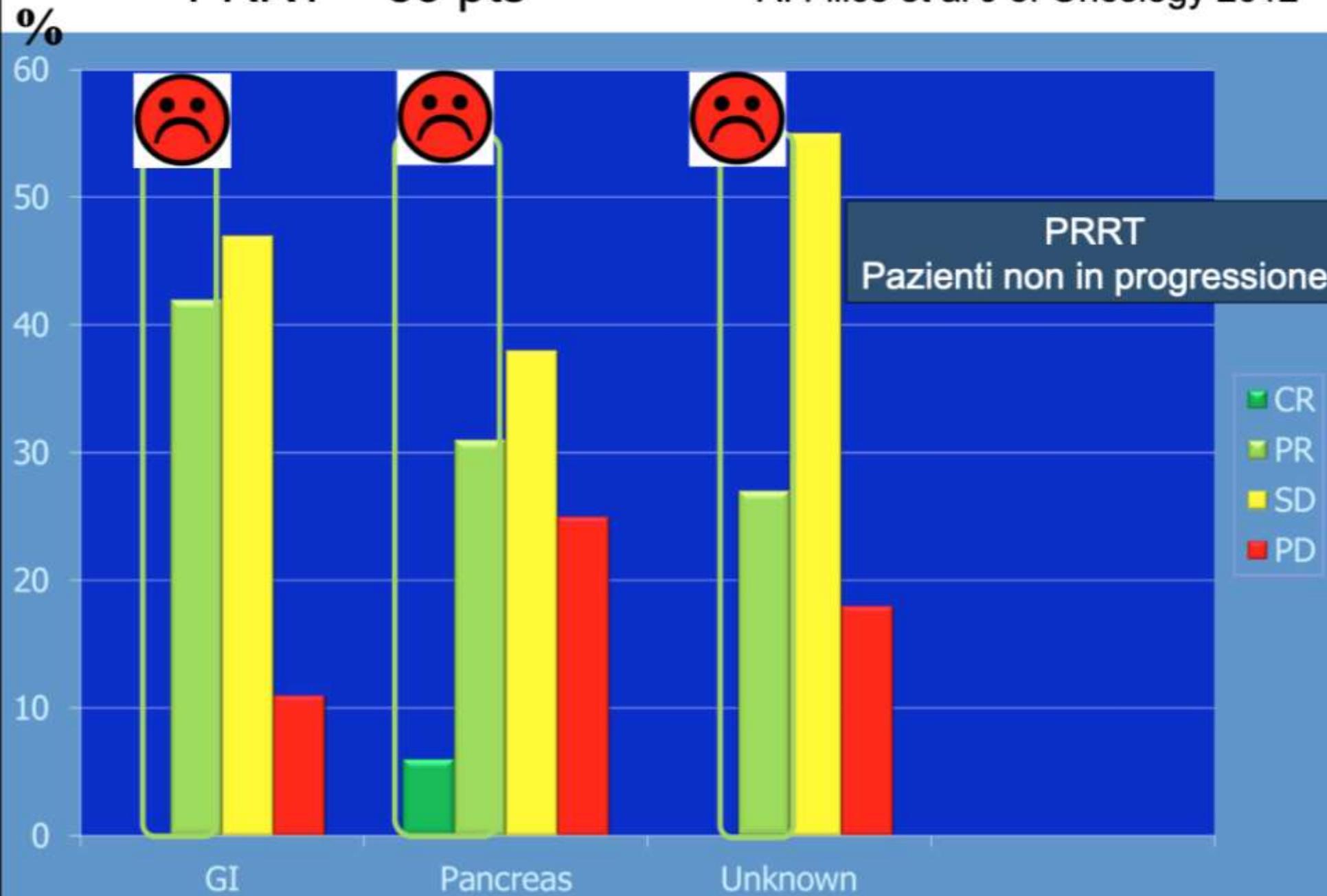
Maddalena Sansovini¹ · Stefano Severi¹ · Annarita Ianniello¹ · Silvia Nicolini¹ · Lorenzo Fantini¹ · Emilio Mezzenga² · Fabio Ferroni³ · Emanuela Scarpi⁴ · Manuela Monti⁴ · Alberto Bongiovanni⁵ · Sara Cingarlini⁶ · Chiara Maria Grana⁷ · Lisa Bodei⁷ · Giovanni Paganelli¹

Eur J Nucl Med Mol Imaging (2017) 44:490–499



PRRT 59 pts

A. Filice et al J of Oncology 2012



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journal homepage: www.elsevier.com/locate/seminoncol



objective response rate
disease control rate
133 panNET

Peptide receptor radionuclide therapy for patients with advanced pancreatic neuroendocrine tumors

John Ramage^a, Boris G. Naraev^b, Thorvardur R. Halfdanarson^{c,*}

^aKings Health Partners Neuroendocrine Centre, London, UK

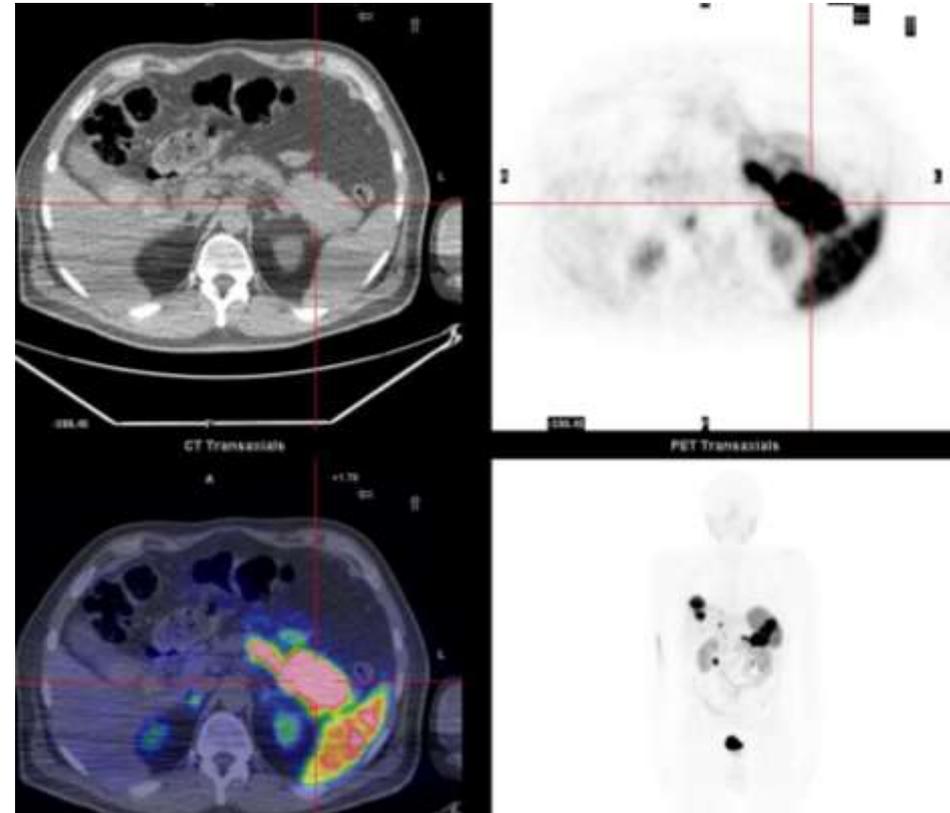
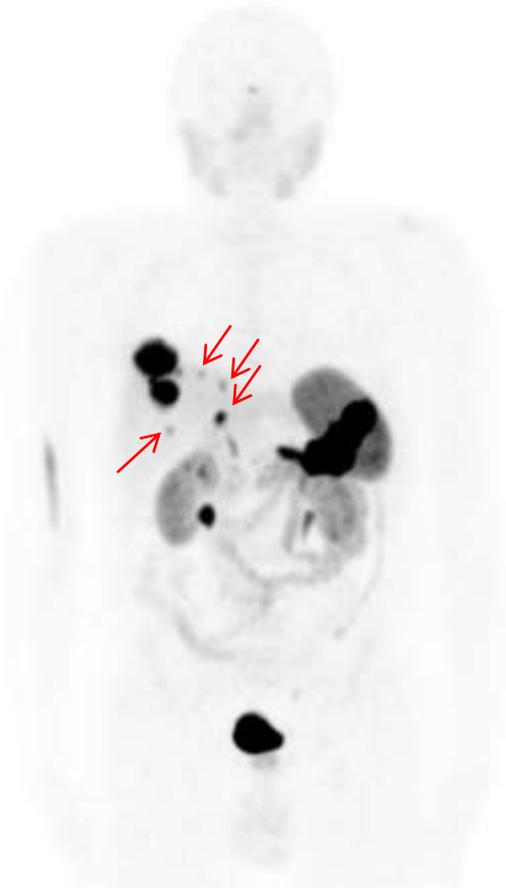
^bBanner MD Anderson Cancer Center, Gilbert, AZ, USA

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Table 3
Studies reporting tumor response and survival outcomes specifically for patients with panNET receiving ¹⁷⁷Lu-DOTATATE PRRT.

Type of study	Reference	Total patient group	Relevant patient group with treatment outcome	Response criteria	CR	PR	MR	SD	PD	ORR	DCR	PFS	OS
					n (%)					median in months (95% CI) ^a			
Retrospective	Brabander 2017 [35]	GEP or bronchial NET with +SSTR imaging (N = 443); 54% with baseline PD	Total panNET (n = 133)	RECIST v1.1	6 (5)	66 (50)	N/A	40 (30)	17 (13)	72 (54)	112 (84)	30	71
			• PanNET with baseline SD (n = 21)		1 (5)	9 (43)	N/A	10 (48)	1 (5)	10 (48)	20 (95)	31	not defined
			• Pan-NET with baseline PD (n = 66)		2 (3)	36 (55)	N/A	15 (23)	10 (15)	38 (58)	53 (80)	31	71
			• F pan-NET (n = 21)		1 (5)	12 (57)	N/A	4 (19)	3 (14)	13 (62)	17 (81)	30	not defined
			• NF pan-NET (n = 112)		5 (4)	54 (48)	N/A	36 (32)	14 (13)	59 (53)	95 (85)	30	69
Expanded access trial	Hamiditabar 2017 [46]	NET with +SSTR imaging and baseline PD (N = 144)	Total panNET (n = 48)	RECIST	0 (0)	6 (13)	N/A	18 (38)	23 (48)	6 (13)	24 (50)	NS	NS
Phase 2	Sansovini 2017 [47]	Unresectable or metastatic G1/G2 panNET with +SSTR imaging and	Total panNET (N = 60)	SWOG	4 (7)	14 (23)	N/A	31 (52)	11 (18)	18 (30)	49 (82)	29 (20–54)	NR

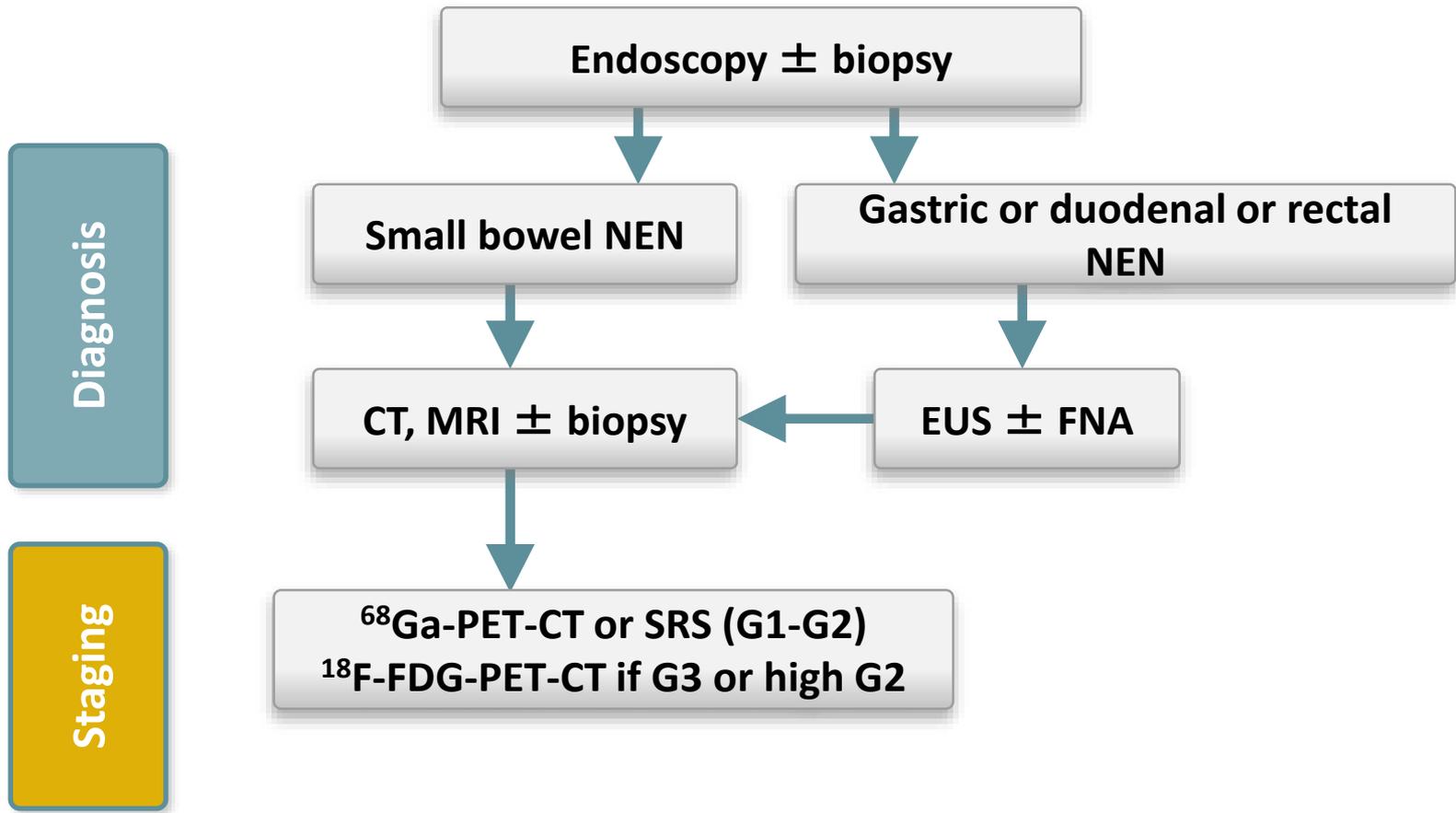
^{68}Ga -DOTATATE PET/CT



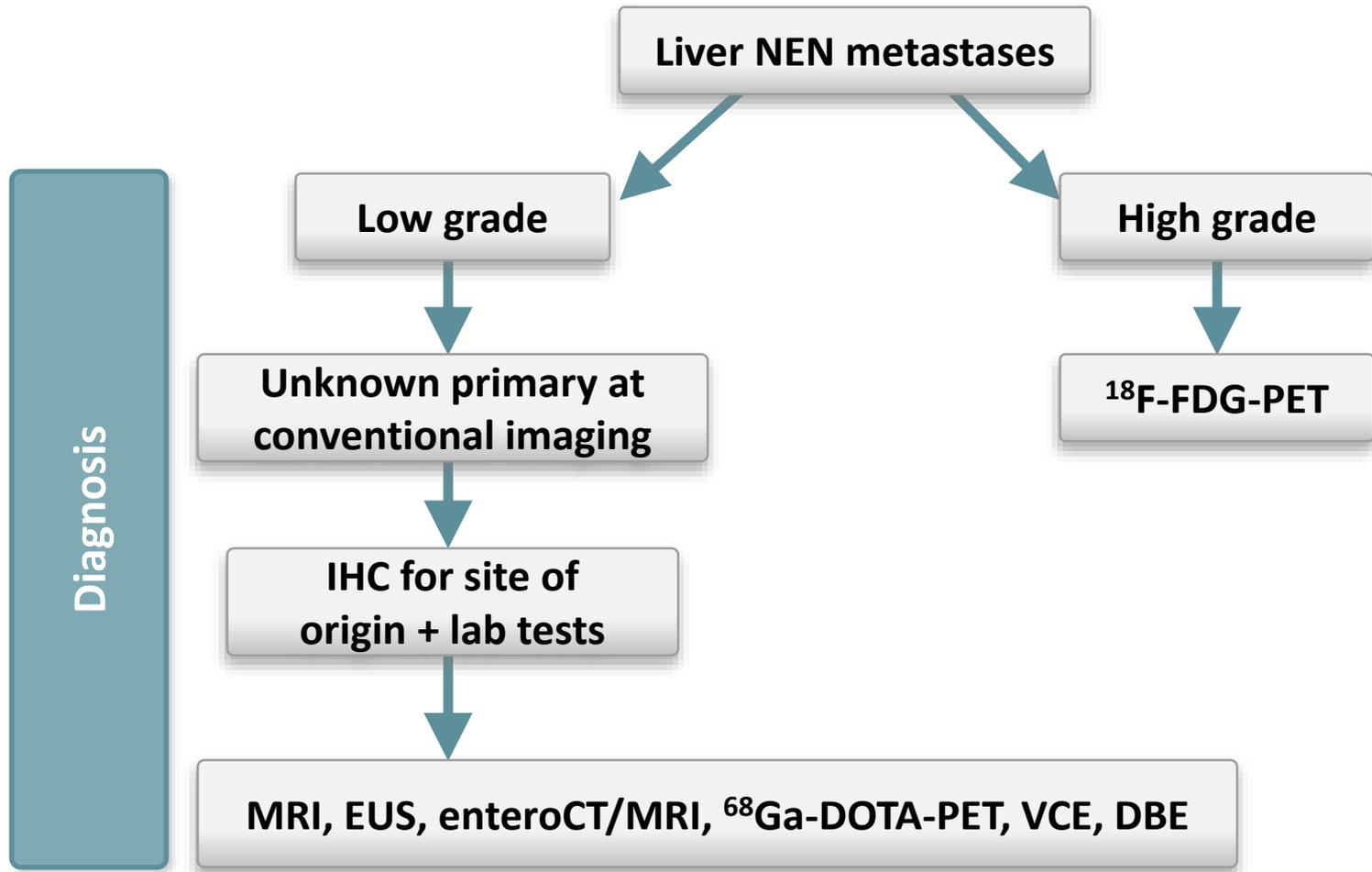
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67 aa

Riscontro occasionale in corso di esame ecotomografico addominale (per calcolosi della colecisti) di metastasi epatiche da ca neuroendocrino del corpo-coda del pancreas

Diagnostic flow-chart for GEP-NEN suspected at endoscopy



Diagnostic flow-chart in the patient with metastatic disease and unknown primary tumor



⁶⁸Ga-DOTATOC Imaging of Neuroendocrine Tumors: A Systematic Review and Metaanalysis

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Michael M. Graham¹, Xiaomei Gu², Timothy Ginader³, Patrick Breheny³, and John J. Sunderland¹

1) Sensibilità e specificità

TABLE 2
Sensitivity and Specificity

Reference	<i>n</i>	True-positive	False-negative	True-negative	False-positive	Sensitivity	Specificity
Gabriel et al. (8)	84	69	2	12	1	97.2%	92.3%
Versari et al. (9)	19	12	1	5	1	92.3%	83.3%
Ruf et al. (10)	51	32	7	8	4	82.1%	66.7%
Mayerhoefer et al. (11)	55	32	1	18	4	97.0%	81.8%
Beiderwellen et al. (12)	8	4	1	3	0	80.0%	100.0%
Schraml et al. (13)	51	40	1	10	0	97.6%	100.0%
Venkitaraman et al. (14)	32	25	1	6	0	96.2%	100.0%
Frilling et al. (15)	52	52	0			100.0%	
Poeppel et al. (19)	40	40	0			100.0%	
Jindal et al. (16)	13	13	0			100.0%	
Kumar et al. (17)	20	20	0			100.0%	
Nakamoto et al. (18)	46	6	1			85.7%	

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2) Confronto ⁶⁸Ga-DOTATOC vs ¹¹¹In Octreotide

The sensitivity of ⁶⁸Ga-DOTATOC PET is definitely better than ¹¹¹In-octreotide SPECT imaging. In the 2 papers that directly compared the 2 approaches, the sensitivity for ⁶⁸Ga-DOTATOC on a per-lesion basis was 100% and for ¹¹¹In-octreotide 78%. In the

TABLE 5
⁶⁸Ga-DOTATOC Versus ¹¹¹In-Octreotide

Reference	n	DOTATOC		Octreotide	
		True-positive	False-negative	True-negative	False-positive
Hofmann et al. (3)	8	40	0	34	6
Buchman et al. (24)	27	70	0	52	18

3) Cambio nel management

review, 3 papers were found that reported change in management after ⁶⁸Ga-DOTATOC PET imaging. The pooled result reported change of management in 95 of 188 (51%), which clearly illustrates

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