

XXXII CONGRESSO NAZIONALE AIRO
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AIRO2022

Radioterapia di precisione per un'oncologia innovativa e sostenibile

BOLOGNA, 25-27 NOVEMBRE
PALAZZO DEI CONGRESSI

 Associazione Italiana
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Detection rate of ^{68}Ga -PSMA PET/CT from a prospective study. PSICHE trial (NCT05022914)



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DICHIARAZIONE

Relatore: Marco Banini

- Posizione di dipendente in aziende con interessi commerciali in campo sanitario: **NIENTE DA DICHIARARE**
- Consulenza ad aziende con interessi commerciali in campo sanitario: **NIENTE DA DICHIARARE**
- Fondi per la ricerca da aziende con interessi commerciali in campo sanitario: **NIENTE DA DICHIARARE**
- Partecipazione ad Advisory Board: **NIENTE DA DICHIARARE**
- Titolarità di brevetti in compartecipazione ad aziende con interessi commerciali in campo sanitario: **NIENTE DA DICHIARARE**
- Partecipazioni azionarie in aziende con interessi commerciali in campo sanitario: **NIENTE DA DICHIARARE**



Background

- **Early biochemical relapse (BR)** after radical prostatectomy (RP) is currently managed with salvage radiotherapy (SRT)
- Novel, **ultrasensitive imaging (PSMA PET/CT)** showed on prospective trials to have an impact on biochemical outcomes after SRT
- EAU 2022 guidelines¹: perform PSMA PET/CT with PSA >0.2 ng/ml if this will influence treatment decisions
- AIRO position paper²: offer ablative RT to metastases in metachronous oligometastatic CSPC, with primary tumor controlled, to defer systemic treatment initiation

1. EAU Guidelines, EAU Annual Congress Amsterdam 2022.

2. D'Angelillo RM, Francolini G, Ingrosso G, et al., Crit Rev Oncol Hematol. 2019



Materials and Methods

Prospective, observational, multicentre study

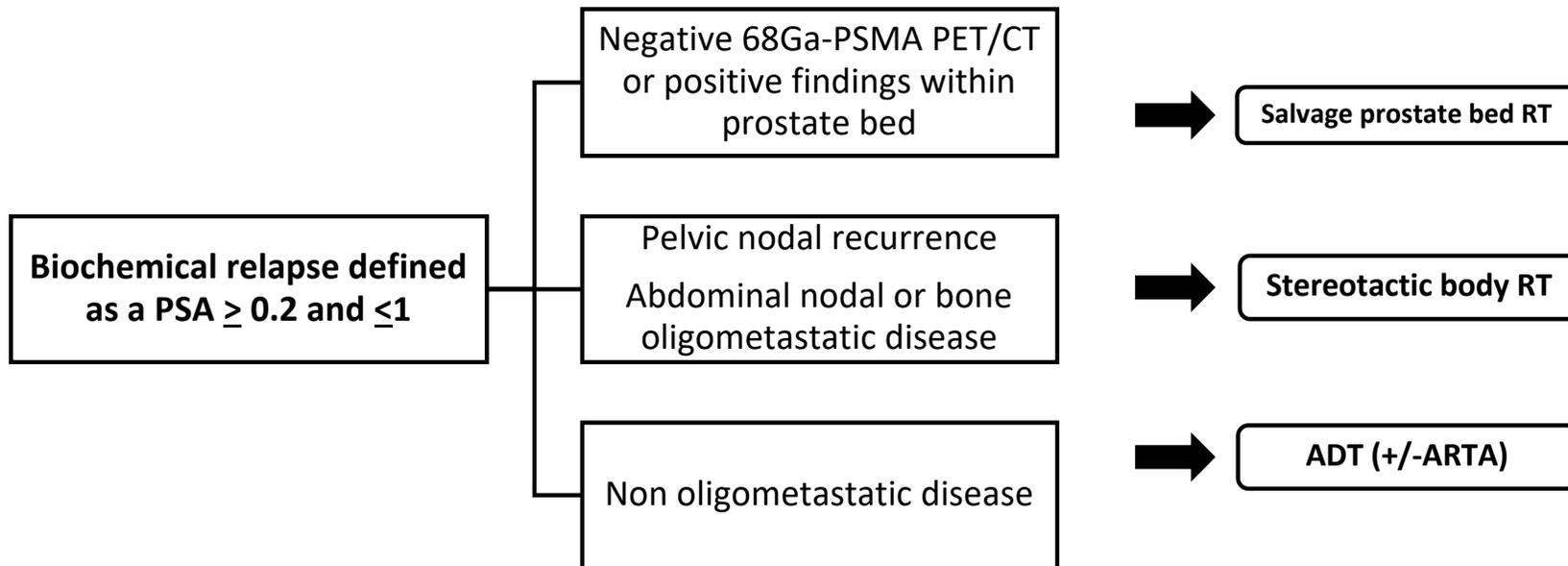
- RP 
- PSA > 0,2 and < 1 ng/ml

- PSA >0,1 ≤ 16 weeks after RP 
- ADT ≤ 6 months prior to enrollment

- Primary EP: 2-yrs PFS (to death, BR or RR)
- Secondary EP: OS, rPFS, 2-yrs QoL (EORTC QLQ-C30 and QLQ-PR25), AE CTCAE 4.0, **impact of PSMA PET/CT on treatment decision (proportion of pts.)**, miRNA analysis
- **Enrollment started 19/03/2021**, target 180 pts.
- **30/07/2022: 100 patients enrolled**, 90 pts sufficient to evaluate management changing in according with PSMA PET/CT results



Procedures: Pre-defined treatment algorithm





Results

Baseline characteristics	
Previous postoperative RT	Yes: 28 (28)
	No: 72 (72)
Age (Median value, IQR)	68 (IQR 62-72)
Baseline T stage (%)	T2b-c: 27 (27)
	T3a-b: 73 (73)
Baseline N stage	N0: 66 (66)
	N1: 4 (4)
	Nx: 30 (30)
Margin status	R0: 57 (57)
	R1: 43 (43)
Baseline ISUP pattern	≤3: 63 (63)
	>3: 37 (37)
Baseline PSA (median, IQR)	8 ng/ml (IQR 5.5-11)
Baseline NCCN risk category	Low: 2 (2)
	Intermediate: 21 (20)
	High: 77 (77)



Post PSMA PET/CT patient management

PSA at recurrence (median value, IQR)	0.37 ng/ml (IQR 0.29-0.51)
PSMA results	Negative/positive within prostate bed: 72 (72)
	Pelvic nodal disease: 23 (23) Abdominal nodal or bone oligometastatic disease: 5 (5)
Number of lesions	0: 72 (72)
	1: 22 (22)
	>1: 6 (6)
Lesion site	Nodal: 22 (22)
	Bone: 5 (5)
	Visceral: 1 (1)
Post PSMA treatment	Observation: 21 (21)
	Prostate bed RT: 50 (50)
	SBRT to nodal disease: 23 (23)
	SBRT to Extrapelvic disease: 5 (5)
	ADT: 1 (1)

- Baseline NCCN high-risk features, pathological stage \geq pT3 and ISUP score $>$ 3 reported a significantly higher rate of positive PSMA PET/CT after restaging (p=0.01, p= 0.02 and p=0.002, respectively). Model significant at multivariate (p=0.01)
- **ISUP score only remained significant at multivariate analysis**

PSA triggering restaging (ng/mL)	Rate of Positive PSMA PET/CT
0,2-0,29	26,9%
0,3-0,37	24%
0,38-0,51	26,9%
0,52-0,98	34,7%



Conclusions

- PSMA PET/CT restaging at BR permitted **tailored treatment out of field of SRT or avoid unnecessary treatment in 28% of patients**
- Restaging based on next generation imaging
- Baseline biological aggressiveness of disease (ISUP score) or miRNA might correlate with pattern of disease recurrence
- **PSICHE trial: Prospective platform of BR management with ultrasensitive modern imaging**
- Study ongoing and first clinical outcomes awaited!

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Thank you for the attention!



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