Short-term high precision radiotherapy for early prostate cancer with concomitant boost to the dominant lesion:

ad interim analysis and preliminary results of phase II trial AIRC-IG-13218

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XXVI Congresso Nazionale AIRO 2016
Farmaci innovativi e iporazionamento

Rational

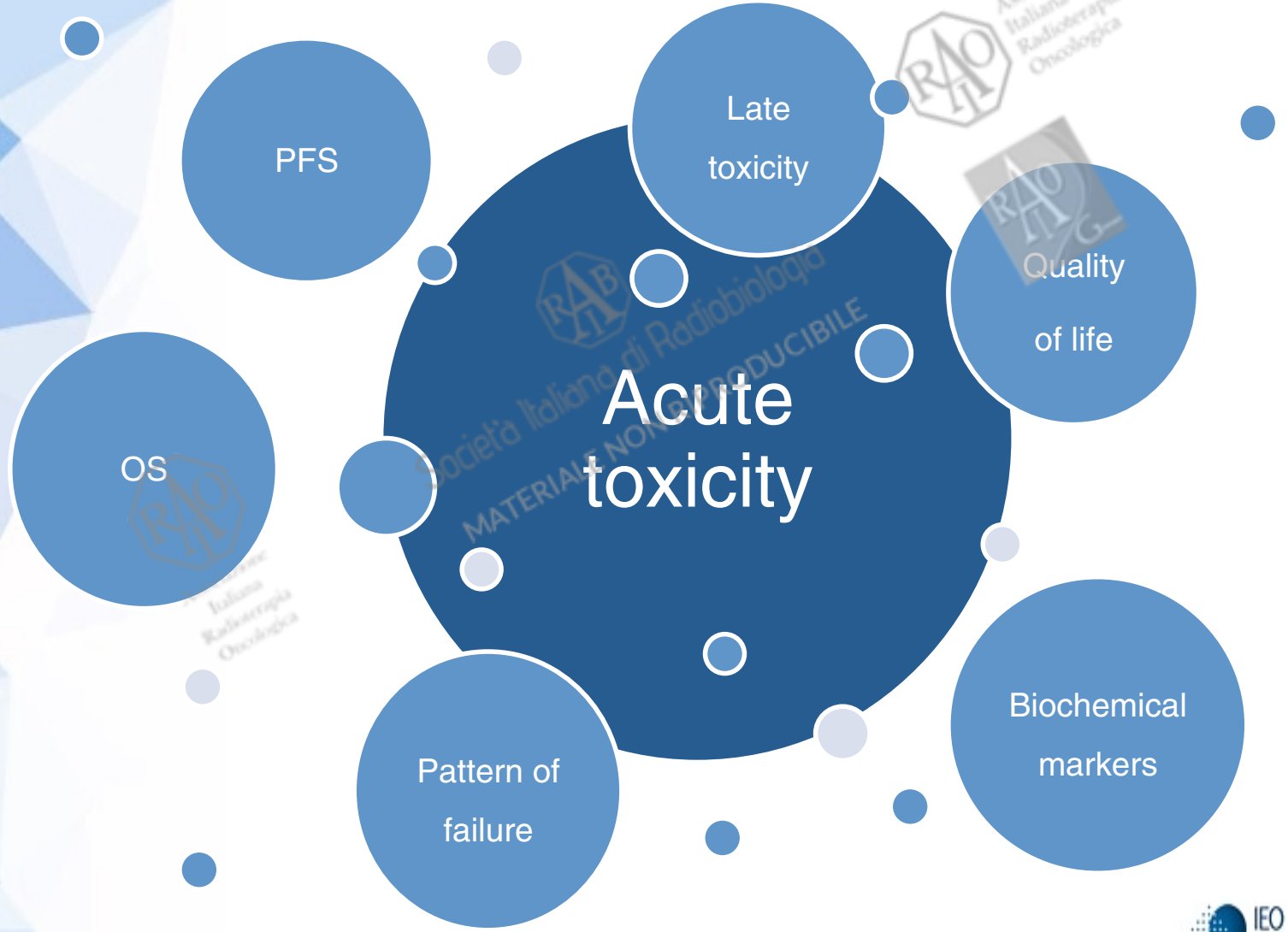
Hypofractionated RT:

- ✓ Appealing for patients and RT-center
  - Well tolerated?

DIL:

- ✓ Cellularity and angiogenesis ↑ then other prostate tissue
  - Could dose escalation to DIL further improve the already good outcomes of patients with early stage PCa?

Aims of the study



Inclusion Criteria	Histologically confirmed prostate adenocarcinoma
	Very low, low and intermediate NCCN risk categories
	Age > 18 years
	Good performance status (Eastern Cooperative Oncology Group - ECOG <2)
	No previous pelvic RT
	No previous prostatectomy
	Good urinary flow (peak flow > 10 ml/s)
	Ability to complete questionnaires about quality of life
Exclusion criteria	Nodal involvement or distant metastasis (cN1 cM1)
	Extracapsular tumor or locally advanced disease (cT3-cT4)
	IPSS questionnaire >20
	Concomitant inflammatory bowel diseases
	Important systemic diseases or oral anticoagulant therapy ongoing
	Non-conformity to dose constraints at the treatment planning
	Previous invasive cancer (apart from non-melanoma skin), unless the patient has been free from disease for at least 3 years
	Mental diseases that can't ensure a valid informed consent

UNIVERSITÀ DEGLI STUDI DI MILANO

IEO Istituto Europeo di Oncologia

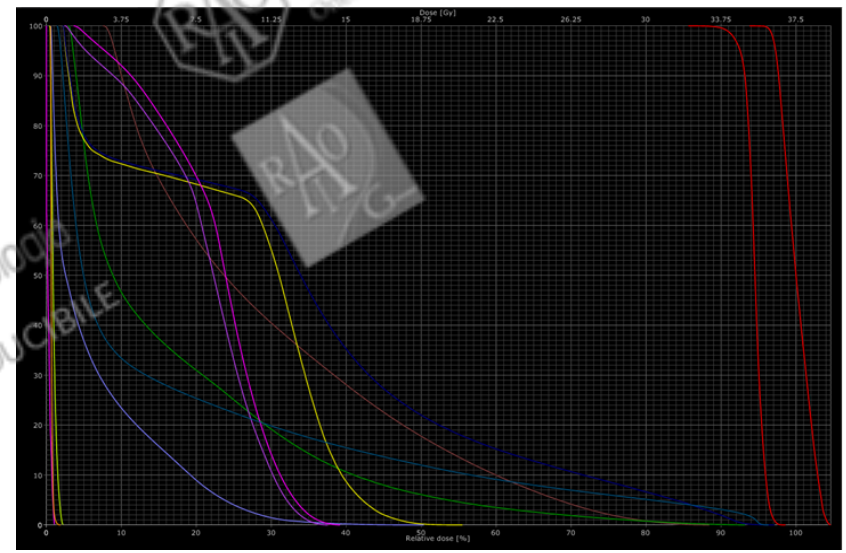
AIRC

Treatment planning

mp-MRI (DWI, DCE, T2W) before the CT treatment simulation in the same treatment position

mp-MRI was co-registered with the planning CT to define the DIL to be boosted

CTV-P = whole prostate (+ sv if intermediate risk)



PTV-P	Margins from CTV	Dose/fr	Total dose	EQD2 (α/β 1.5)
PTV-P	5 mm, 3 mm post	7.25 Gy	36.25 Gy	90.6 Gy
PTV-DIL	3 mm	7.5 Gy	37.5 Gy	96.4 Gy

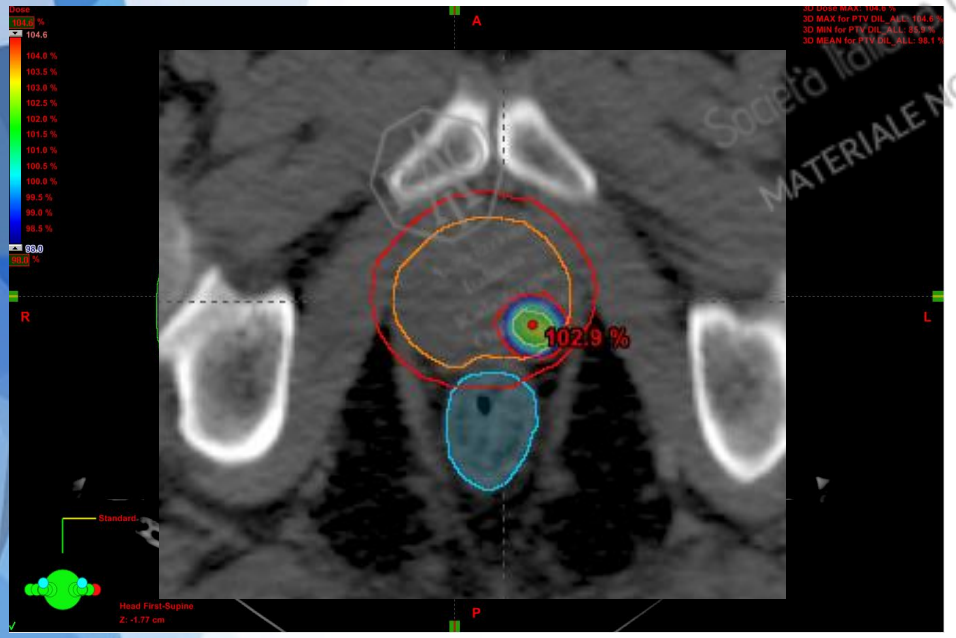
Treatment delivery

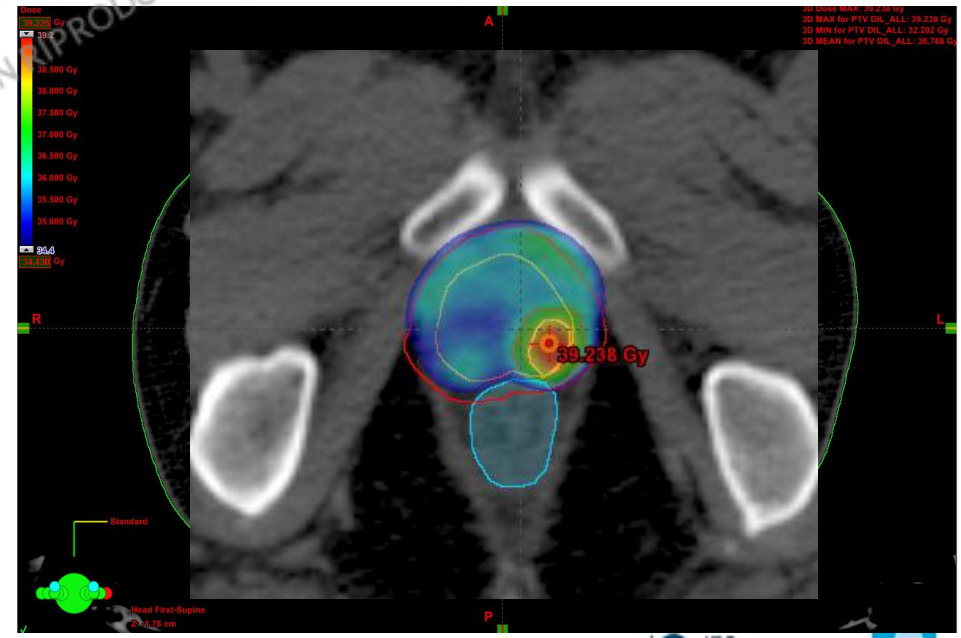
Trilogy™ with RapidArc® technology

IGRT – CBCT

Empty rectum and full bladder

α-1 blockers and low doses of steroids





Patients' characteristics

Median clinical follow-up is 5.9 months (range 1-6).

Number of patients	13
Median age (years)	75.4 (62.7-79.9)
Median initial PSA (ng/ml)	5.8 (4.3-17)
Median Gleason Score	6 (6-7)
Low risk (according to NCCN)	3
Intermediate risk (according to NCCN)	10
Androgen deprivation therapy	1

Toxicity

Follow-up time	Type of toxicity	Grade	Occurrences
End of the treatment	Gastrointestinal	0	12
		1	0
		2	1
	Genitourinary	0	9
		1	4
		2	0

Follow-up time	Type of toxicity	Grade	Occurrences
At one month	Gastrointestinal	0	11
		1	2
		2	0
	Genitourinary	0	9
		1	4
		2	0

Conclusions

Extreme-hypofractionated dose escalation using concomitant boost to mp-MRI-identified DIL is feasible and safe

The study will continue until the enrollment of 65 patients will be reached

A biological substudy has been started, performing mp-MRI-guided biopsies of the DIL in order to establish the potential role of molecular markers as prognostic factors

Work in progress

June 2015 - Sep 2016: 40 pz, 1 drop-out
Median FU: 6.4 mo (4-12.9)

FU at 1 mo	31 pz
G2	2 pz (GU)
G3	1 pz (GU)
FU at 6 mo	17 pz
Tox ≥ G2	0
FU at 12 mo	5
Tox ≥ G2	0
Biochemical failure	0