Phase I study of Stereo-Ablative Radiotherapy with the use of SpaceOAR hydrogel as Definitive Treatment of Prostate Cancer: Preliminary Experience.

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Purpose

Ultrahypofractionation according to Timmerman experience with 9 Gy per fraction (F) times 5 (total 45 Gy in 2.5 weeks) is a feasible dose for the stereo-ablative treatment of prostate cancer , but potentially toxic for rectal mucosa . The introduction of space-oar gel in the prostate-rectum interface controls rectal radiation injury.

Materials/Methods

Age < 80 y P.S. 0-1 (f.up mean 12 m)
histologically proven diagnosis
No adenopathy by CT o MRI or [^{18}F]fluorocholine PET/CT
Stage: T1a-T2C
Gleason score: 3+3 PSA ≤ 20 ng/ml
7 PSA ≤ 15 ng/ml
Non rectal disease (es. ulcerative proctitis)
(all were verified by endoscopy)
Space-OAR gel and 3 fiducial markers were implanted

Exclusion Criteria

CT3b
Positive extrapelvic Pet-colina up-take
Respiratory/liver failure
Myocardial inf. within 6 months
Serious infections
Psychiatric illness
Previous pelvic radiotherapy
Previous or concomitant chemotherapy

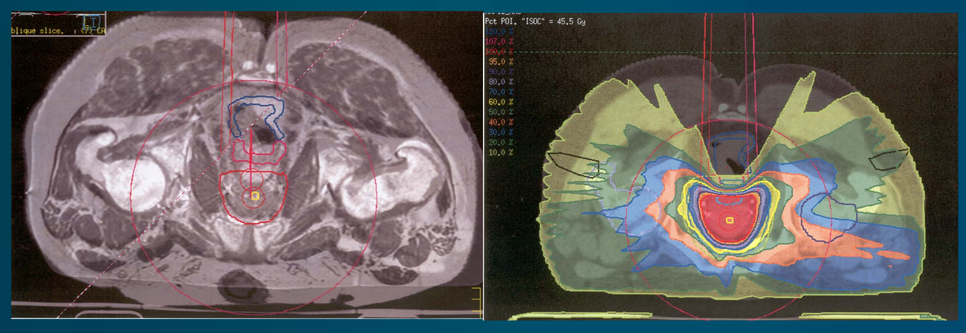
Patients characteristics: 18 pts

mean age:		**74 y (62-81)**
clinical stage:	**T1**	**5**
	T2a	**8**
	T2b	**4**
	T2c	**1**
Gleason –Score		
	6	**13**
	7	**5**
mean ptv volume	**70.7**	**(31.8-157.7)**

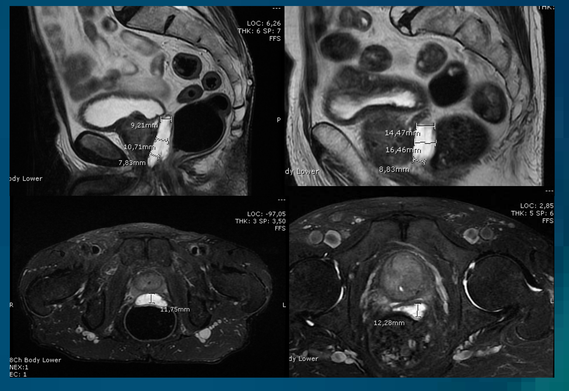
Set-Up procedures

- **3 gold intraglandular seeds**
- **Space-OAR injection**
- **Pelvic thermoplastic mask**
- **CT scan (3 mm thickness)**
- **Each fraction with CBCT and on-line alignment**

TC-MRI fusion contouring and VIMAT plan



Symmetric and Asymmetric implant



volume definition plan

- **Anterior rectal wall (without content)**
- **Posterior rectal wall**
- **Bladder wall**
- **Urethral lumen + 1-2 mm.**
- **femoral heads, skin (folds),**
- **cauda eq.ples.sacr. nerves**
- **CTV Prostata without sem. vesc.**
- **PTV + 3 mm rectal side**
  + 5 mm axial expansion
  + 10 mm cran.caudal expantion

schedule

1 week 2 week 3 week

↑ ↑ ↑ ↑ ↑

dose/fr. **900 cGy x 5 F**
tot. 45 Gy

BED **1.5 147.8 Gy**
(Univ. Surv. Equiv. Dose)

Planning Parameters

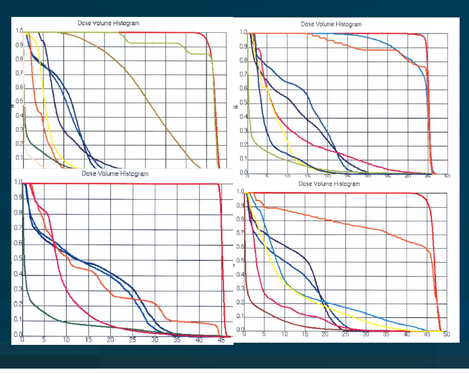
VIMAT tecnique
external PTV is covered by 80% isodose line (60-90%)
Isodose line PTV prescription is 95%
99% of the PTV receives il 90% of the dose
Hot spot inside
(is higher if lower is the isodose of prescription)
Conform. Index: < 1.3
(prescription volume/ PTV volume)

Mean gel displacement

rectum	SUP.	MED.	INF.
	12.9	**14.3**	**9.3**

Anterior- rectal volume dose :
15.3 Gy (7.95-29.5)

DVH examples



Acute toxicity (CTCAE criteria)

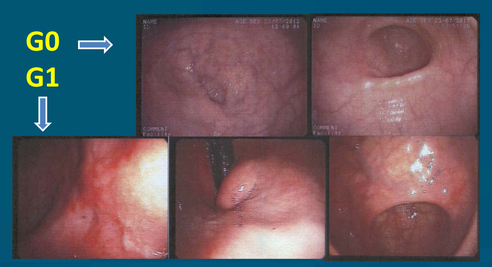
	0	1	2	≥ 3
GI	86%	14%	0	0
GU	73%	27%	0	0

Late toxicity (15 pts) (CTCAE criteria)

	0	1	2	≥ 3
GI	86%	14%	0	0
GU	94%	6%	0	0

Rectoscopy after 10 days

G0 ⇨
G1 ⇩



Conclusions

Our preliminary data suggest that this SABR program with the use of Space-OAR gel can reduce dramatically the acute rectal mucosal toxicity because of his displacement far from the PTV, and allow to treat bigger PTV volume (more than 60 gr.) otherwise excluded in no-gel population; also late rectal toxicity was minimal; this allows to apply Timmerman ultra-ipofractionation regimen in the planned time in wider prostatic cancer presentations offering a well tolerated short course of radiotherapy. We need more follow-up for testing the biochemical control .