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) historically proven diagnosis
- No adenopathy by CT o MRI or [18F]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)
- CT scan (3 mm thickness)
- Each fraction with CBCT and on-line alignment

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
- 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

Symmetric and Asymmetric implant

TC-MRI fusion contouring and VIMAT 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 exapntion

VIMAT technique

- 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

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

Mean gel displacement

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

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-hipofractionation 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.