TEN-C

Trial Schema

Eligibility

 Low/Intermediate risk PCa (exclude if all intermediate risk factors present*)

- No androgen deprivation therapy
- Baseline erectile potency by EPIC sexual domain 60-100
- No lesion** within 5mm of 1 neurovascular bundle by MRI
- * cT2h-cT2c Gleason 7 >50% cores involved PSA >10 ** MRI PIRADS v2.0 Score 3-5 is defined as a 'lesion' *** Recommend CT w/ IV contrast push to simulate arteriogram

Registration: Rectal SpaceOar & fiducials

- Labs • FPIC
- baseline CT/MR*** simulation &
- delineation of neurovascular structures for sparing in all pt
 - N=120 pts
 - 15% attrition, stdey 20. effect size 0.50, alpha 0.1

· 2-year decline in EPIC

Stratify Neurovascular sparing RANDOMIZE SAhR with dose- FPIC sexual domain score painting approach >80 vs 60-79

 Institution Baseline sexual aid or

medication use Diahetes

sexual domain



Secondary endpoints:

. Biochemical failure DMES CSS Other HROOL EPIC domains.

Standard SAbR

Dose 40 - 45 Gy / 5 fractions

· Comparison of both arms vs. historical SBRT prostate control without rectal spacer

Patient talking points



While achieving high survival rates, standard surgery or radiation for localized prostate cancer results in erectile dysfunction (ED) or loss of sexual function in 50% or more of men



Nerves and blood vessels supplying the penis surround the prostate and are damaged during radiation or surgery



In this study, we are testing the ability of SAbR, a highly focused radiation technique, with detailed MR imaging and a rectal spacer hydrogel (SpaceOAR®, Augmenix) to spare these neurovascular elements and hopefully reduce ED



If you choose to participate, you will be randomly offered either standard SAbR therapy or SAbR with reduced dose to neurovascular structures and followed with quality of life questionnaires.



A phase II randomized controlled trial of stereotactic ablative body radiotherapy (SAbR) with or without neurovascular sparing for erectile function preservation in localized prostate cancer (6/2018 V5)

Eligibility Summary (see protocol for full criteria)



AJCC 7th cT1-T2N0M0 (DRE optional)

Gleason 6-7 (template bx recommended. If only fusion bx, all PIRADS v2 score 4-5

must be sampled)

Serum PSA ≤20 ng/mL

Baseline AUA symptom score ≤19

EPIC sexual domain composite score 60-100 (Key inclusion)

mpMRI prostate required with confirmed >5mm minimum distance from at least once side's neurovascular bundle to nearest lesion (defined PIRADS v2 score 3-5). See example image.

Gland size ≤80 gm (consider cytoreduction for >60gm size)

No androgen deprivation therapy

No significant penile malformation or implant

Men must not require ED medication or device to achieve erections sufficient for intercourse.

No prior TURP

Testosterone >280 ng/dL

MRI equivocal ECE opposite to spared side allowed at investigator discretion

Pts <u>may not</u> have all 3 int risk features (PSA >10, cT2b-c, Gleason 7) AND ≥50% template cores involved

Experimental contouring schema to spare low risk for involvement prostate (area between red lines) near NVB (blue)

