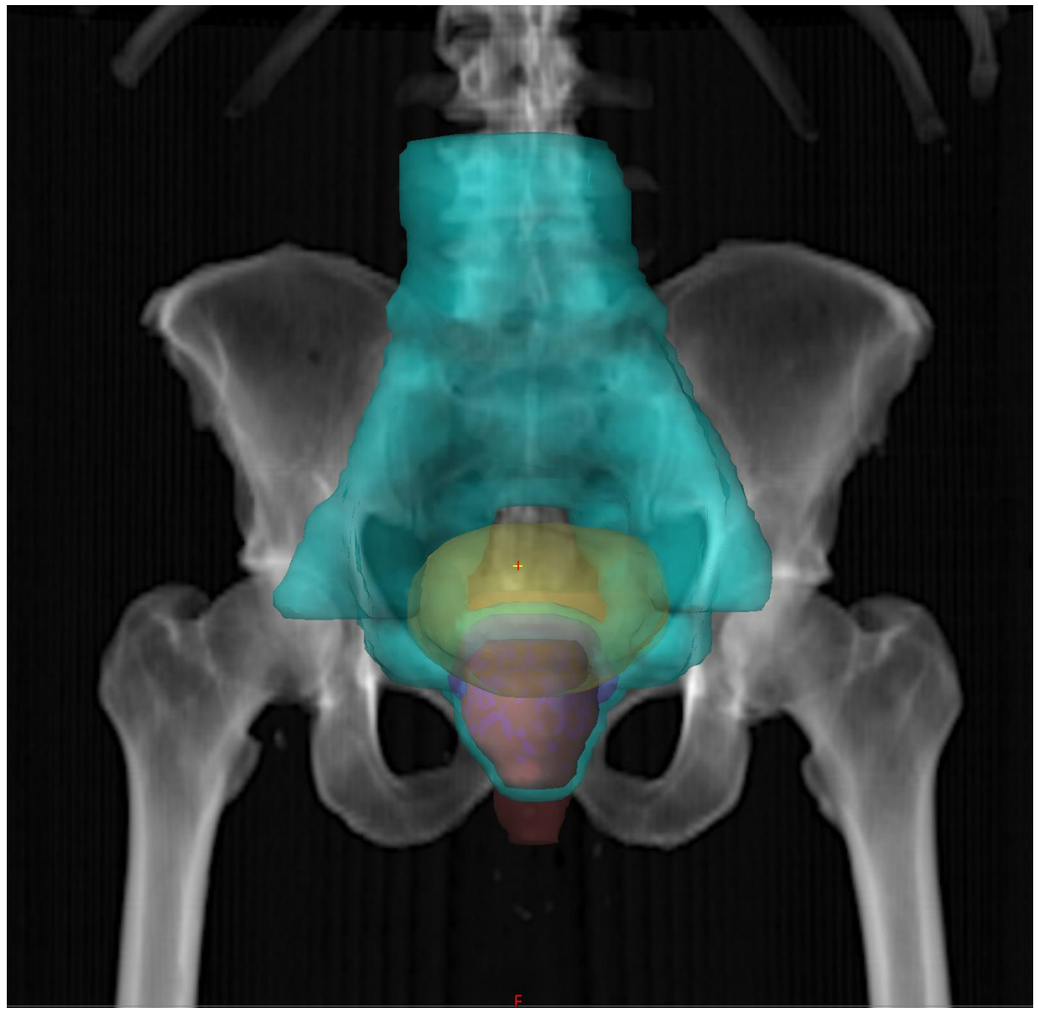

Expanding SBRT to High Risk Prostate Cancer

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Disclosures

Speaking Honorarium

Received honorarium and travel support for participation in this meeting

Research Collaborations

Montefiore Medical Center maintains ongoing research collaboration agreements with Accuray and Varian Medical Systems

Presentation Overview

1 **Introduction**

Disease classification in Prostate Cancer

2 **Risk of Nodal Involvement**

Roach Formula
Role of PSMA PET-CT

3 **SBRT for High-Risk Patients**

Recent clinical data
Ongoing trials

4 **Challenges of Treatment**

5 **Open Discussion**

Is there room to improve

NCCN Prostate Cancer Guidelines Version 4.2026

INITIAL RISK STRATIFICATION AND STAGING WORKUP FOR CLINICALLY LOCALIZED DISEASE

Risk Group	Clinical/Pathologic Features (Staging, ST-1)		
Low[j]	Has all of the following: • cT1–cT2a • Grade Group 1 • PSA <10 ng/mL		
Intermediate[j]	Has all of the following: • No high-risk group features • No very-high-risk group features • Has one or more intermediate risk factors (IRFs): ▸ cT2b–cT2c ▸ Grade Group 2 or 3 ▸ PSA 10–20 ng/mL	Favorable intermediate	Has all of the following: • 1 IRF • Grade Group 1 or 2 • <50% biopsy cores positive (eg, <6 of 12 cores)[k]
		Unfavorable intermediate	Has one or more of the following: • 2 or 3 IRFs • Grade Group 3 • ≥50% biopsy cores positive (eg, ≥6 of 12 cores)[k]
High	Has one or more high-risk features, but does not meet criteria for very high risk: • cT3–cT4 • Grade Group 4 or Grade Group 5 • PSA >20 ng/mL		
Very high	Has at least two of the following: • cT3–cT4 • Grade Group 4 or 5 • PSA >40 ng/mL		

American Joint Committee on Cancer (AJCC)
TNM Staging System For Prostate Cancer (8th ed., 2017)
***Table 1.* Definitions for T, N, M**
Clinical T (cT)

T	Primary Tumor
TX	Primary tumor cannot be assessed
T0	No evidence of primary tumor
T1	Clinically inapparent tumor that is not palpable
T1a	Tumor incidental histologic finding in 5% or less of tissue resected
T1b	Tumor incidental histologic finding in more than 5% of tissue resected
T1c	Tumor identified by needle biopsy found in one or both sides, but not palpable
T2	Tumor is palpable and confined within prostate
T2a	Tumor involves one-half of one side or less
T2b	Tumor involves more than one-half of one side but not both sides
T2c	Tumor involves both sides
T3	Extraprostatic tumor that is not fixed or does not invade adjacent structures
T3a	Extraprostatic extension (unilateral or bilateral)
T3b	Tumor invades seminal vesicle(s)
T4	Tumor is fixed or invades adjacent structures other than seminal vesicles such as external sphincter, rectum, bladder, levator muscles, and/or pelvic wall.

Pathological T (pT)

T	Primary Tumor
T2	Organ confined
T3	Extraprostatic extension
T3a	Extraprostatic extension (unilateral or bilateral) or microscopic invasion of bladder neck
T3b	Tumor invades seminal vesicle(s)
T4	Tumor is fixed or invades adjacent structures other than seminal vesicles such as external sphincter, rectum, bladder, levator muscles, and/or pelvic wall

Note: There is no pathological T1 classification.
Note: Positive surgical margin should be indicated by an R1 descriptor, indicating residual microscopic disease.

N	Regional Lymph Nodes
NX	Regional lymph nodes cannot be assessed
N0	No positive regional nodes
N1	Metastases in regional node(s)

M	Distant Metastasis
M0	No distant metastasis
M1	Distant metastasis
M1a	Nonregional lymph node(s)
M1b	Bone(s)
M1c	Other site(s) with or without bone disease

Note: When more than one site of metastasis is present, the most advanced category is used. M1c is most advanced.

***Table 2.* AJCC Prognostic Groups**

Group	T	N	M	PSA (ng/mL)	Grade Group
Stage I	cT1a-c	N0	M0	PSA <10	1
	cT2a	N0	M0	PSA <10	1
	pT2	N0	M0	PSA <10	1
Stage IIA	cT1a-c	N0	M0	PSA ≥10 <20	1
	cT2a	N0	M0	PSA ≥10 <20	1
	pT2	N0	M0	PSA ≥10 <20	1
	cT2b	N0	M0	PSA <20	1
	cT2c	N0	M0	PSA <20	1
Stage IIB	T1-2	N0	M0	PSA <20	2
Stage IIC	T1-2	N0	M0	PSA <20	3
	T1-2	N0	M0	PSA <20	4
Stage IIIA	T1-2	N0	M0	PSA ≥20	1-4
Stage IIIB	T3-4	N0	M0	Any PSA	1-4
Stage IIIC	Any T	N0	M0	Any PSA	5
Stage IVA	Any T	N1	M0	Any PSA	Any
Stage IVB	Any T	Any N	M1	Any PSA	Any

Note: When either PSA or Grade Group is not available, grouping should be determined by T category and/or either PSA or Grade Group as available.

Histopathologic Type
This classification applies to adenocarcinomas and squamous carcinomas, but not to sarcoma or transitional cell (urothelial) carcinoma of the prostate. Adjectives used to describe histologic variants of adenocarcinomas of prostate include mucinous, signet ring cell, ductal, and neuroendocrine, including small cell carcinoma. There should be histologic confirmation of the disease.

Definition of Histologic Grade Group (G)
Recently, the Gleason system has been compressed into so-called Grade Groups.

Grade Group	Gleason Score	Gleason Pattern
1	≤6	≤3+3
2	7	3+4
3	7	4+3
4	8	4+4, 3+5, 5+3
5	9 or 10	4+5, 5+4, 5+5

High	Has one or more high-risk features, but does not meet criteria for very high risk: • cT3–cT4 • Grade Group 4 or Grade Group 5 • PSA >20 ng/mL
Very high	Has at least two of the following: • cT3–cT4 • Grade Group 4 or 5 • PSA >40 ng/mL

T3	Extraprostatic tumor that is not fixed or does not invade adjacent structures
T3a	Extraprostatic extension (unilateral or bilateral)
T3b	Tumor invades seminal vesicle(s)
T4	Tumor is fixed or invades adjacent structures other than seminal vesicles such as external sphincter, rectum, bladder, levator muscles, and/or pelvic wall.

Grade Group	Gleason Score	Gleason Pattern
4	8	4+4, 3+5, 5+3
5	9 or 10	4+5, 5+4, 5+5

PRINCIPLES OF RADIATION THERAPY

Table 1: Below are examples of regimens that have shown acceptable efficacy and toxicity. The optimal regimen for an individual patient warrants evaluation of comorbid conditions, voiding symptoms, and toxicity of therapy. Additional fractionation schemes may be used as long as sound oncologic principles and appropriate estimate of BED are considered.

See treatment pages and Principles of ADT (PROS-G) for other recommendations, including recommendations for neoadjuvant/concomitant/adjuvant ADT.

EBRT Regimen	Preferred Dose/Fraction	Definitive RT						Post-Treatment RT			Advanced Disease	
								Post-RP		Post-RT	Primary Tumor	Metastases
		Low	FIR	UIR	High	Very-High	Regional	aRT	sRT	sRT	mCSPC M0 CRPC mCRPC	MDT
Conventional	1.8–2 Gy x 37–45 fx			☼	☼	✓	✓				☼	
	1.8–2 Gy x 30–39 fx							✓	✓		☼	
Moderate Hypofractionation	3 Gy x 20 fx (preferred)[a] 2.7 Gy x 26 fx 2.5 Gy x 28 fx	☼	✓	✓	✓	✓	✓			☼	☼	☼
	2.63–2.75 Gy x 20 fx 2.5 Gy x 25 fx							✓	✓	☼	✓	☼
Ultra Hypofractionation (SBRT)	9.5 Gy x 4 fx 7.25–8 Gy x 5 fx 6 Gy x 6 fx 6.1 Gy x 7 fx	☼	✓	✓	✓	☼	☼		☼	✓	✓	✓
	9–10 Gy x 3 fx 12 Gy x 2 fx 16–24 Gy x 1 fx											✓
	6.2–6.4 Gy x 5 fx								☼			
EBRT Boost Techniques												
EBRT with simultaneous integrated boost	See footnote b.		☼	✓	✓	☼	☼		☼	☼	☼	
EBRT with sequential SBRT boost	*Prostate:* 1.8 Gy x 23–28 fx *Boost:* 6 Gy x 3 fx 9.5 Gy x 2 fx			☼	☼	☼						

(✓ Preferred; ☼ Acceptable based on clinical and medical need; Regimens shaded gray are not recommended)

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PRINCIPLES OF RADIATION THERAPY

Definitive RT (continued)

- **High Risk**
  - The target should include the prostate and the seminal vesicles (full).
  - RT options include EBRT or brachytherapy boost combined with EBRT. Carefully selected patients may receive brachytherapy monotherapy.
  - Focal boosting with isotoxic delivery can be considered if there is sufficient provider and practice expertise to delineate the DIL and OARs on MRI.[9]
  - Clinical trials have demonstrated varied results regarding the benefit of ENI. Multiple randomized trials have not demonstrated improvement in outcomes from ENI. However, the benefit of ENI was shown in one trial of patients with high-risk prostate cancer staged primarily with PSMA-PET/CT and who had a risk of nodal involvement >20%. Currently, the use of ENI is at the discretion of the treating physician.
  - ADT (level 1 data for LT-ADT 12–36 months) is recommended for patients with life expectancy >5 years or who are symptomatic unless medically contraindicated. Radiotherapy dose or modality has not clearly demonstrated the ability to obviate the benefit of LT-ADT.[10]

- **Very-High-Risk**
  - The target should include the prostate and the seminal vesicles (full).
  - RT options include EBRT. Carefully selected patients may receive EBRT with a brachytherapy boost.
  - Focal boosting with isotoxic delivery can be considered if there is sufficient provider and practice expertise to delineate the DIL and OARs on MRI.
  - Combination brachytherapy boost with EBRT should not be used routinely. The primary randomized evidence to recommend combination brachytherapy boost with EBRT comes from the ASCENDE-RT trial, which excluded patients with PSA >40 ng/mL and T3b.[12]
  - ADT (level 1 data for LT-ADT 18–36 months) is recommended for patients with life expectancy >5 years or who are symptomatic unless medically contraindicated.
  - Currently, the use of ENI is at the discretion of the treating physician.
  - Addition of abiraterone should be used very selectively as the benefit in contemporary practice with modern staging is uncertain (see PROS-6 and PROS-G 1 of 5).[13] It is not recommended to be used routinely for patients with solely MRI defined T3a disease with low volume Gleason 8 disease. Studies validating the post-hoc subset analysis of STAMPEDE for the benefit of abiraterone in very high-risk prostate cancer using other ARPIs have not yet reported, and thus the benefit of using ARPIs with RT+LT-ADT remains uncertain in contemporary patients with very high risk N0M0 disease. Radiotherapy dose or modality has not clearly demonstrated the ability to obviate the benefit of LT-ADT.[10]

- **Regional Disease**
  - EBRT is recommended to include the prostate, seminal vesicles, and pelvic lymph nodes.
  - Simultaneous integrated boost to involved lymph nodes is recommended while respective adjacent OAR dose constraints.
  - Use of a brachytherapy boost is not recommended in these patients.
  - Addition of abiraterone is recommended (see PROS-7 and PROS-G [1 of 5]).[13]

References on PROS-J 10 of 11

Note: All recommendations are category 2A unless otherwise indicated.

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Risk of Pelvic Lymph Node Involvement

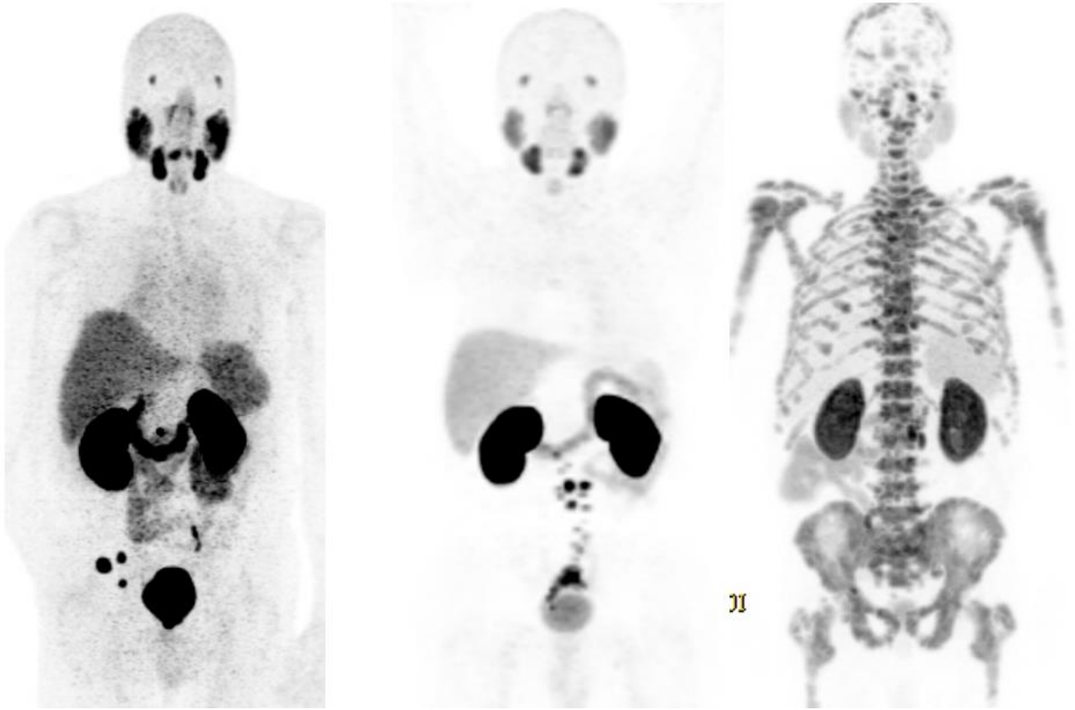
"Roach Equation" - A simple equation for estimating the risk of positive lymph nodes was empirically derived from a nomogram published by Partin et al. demonstrating the value of combining the pre-treatment prostate specific antigen and Gleason Score in predicting the risk of lymph node metastasis for patients with clinically localized prostate cancer. The risk of positive nodes (NS) was calculated using the equation; N+ = (2/3*PSA) + (GS - 6) X 10, where PSA and GS are the pre-treatment prostate specific antigen and Gleason Score respectively, and the calculated risk is constrained between O-65% for a PSA < 40 ng/ml (as in the nomogram).

Classification	PSA	Grade Group	Gleason Score	Risk
Low	<10	1	≤6	<6.7%
Intermediate	<20	2-3	7	<23.3%
High	≥20	4-5	8-10	≥33.3%
Very High	≥40	4-5	8-10	≥46.7%

Research authors: Mack Roach III, Carol Marquez, Hae-Sook Yuo, Perinchery Narayan, Lorie Coleman, Unyime O. Nseyo, Zarrin Navvar, Peter R. Carrol

Role of PSMA PET-CT

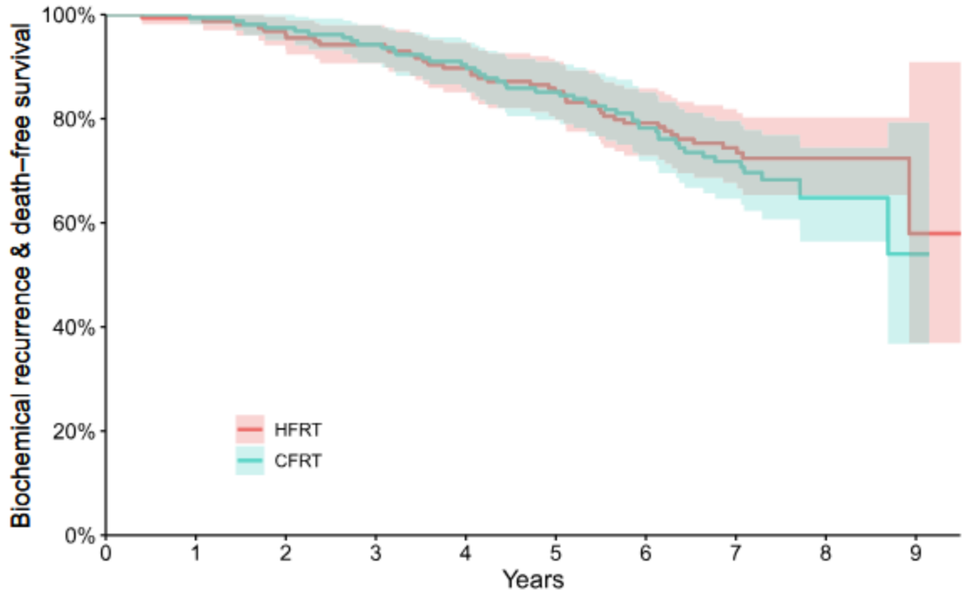
Mazzon et al. 2025 – Meta analysis of 12 and 99 studies, with a total of 1533 and 18 649 participants, respectively, for intraprostatic diagnosis and staging. Reported good accuracy of PSMA PET to discriminate clinically significant prostate cancer, particularly when added to MRI, but negative predictive value alone is insufficient to omit a biopsy. Regarding staging, PSMA PET cannot be used alone to determine the need for lymph node dissection (LND) and should be combined with additional clinical information within predictive tools. As such, further research should develop and validate models that incorporate PSMA PET to reliably inform biopsy or LND.



Elio Mazzone et. al. A Comprehensive Systematic Review and Meta-analysis of the Role of Prostate-specific Membrane Antigen Positron Emission Tomography for Prostate Cancer Diagnosis and Primary Staging before Definitive Treatment, European Urology, Volume 87, Issue 6, 2025, https://doi.org/10.1016/j.eururo.2025.03.003.

Hypofractionated Dose Escalation Radiotherapy for High-Risk Prostate Cancer: the survival analysis of the Prostate Cancer Study-5 (PCS-5), a GROUQ-led phase III trial

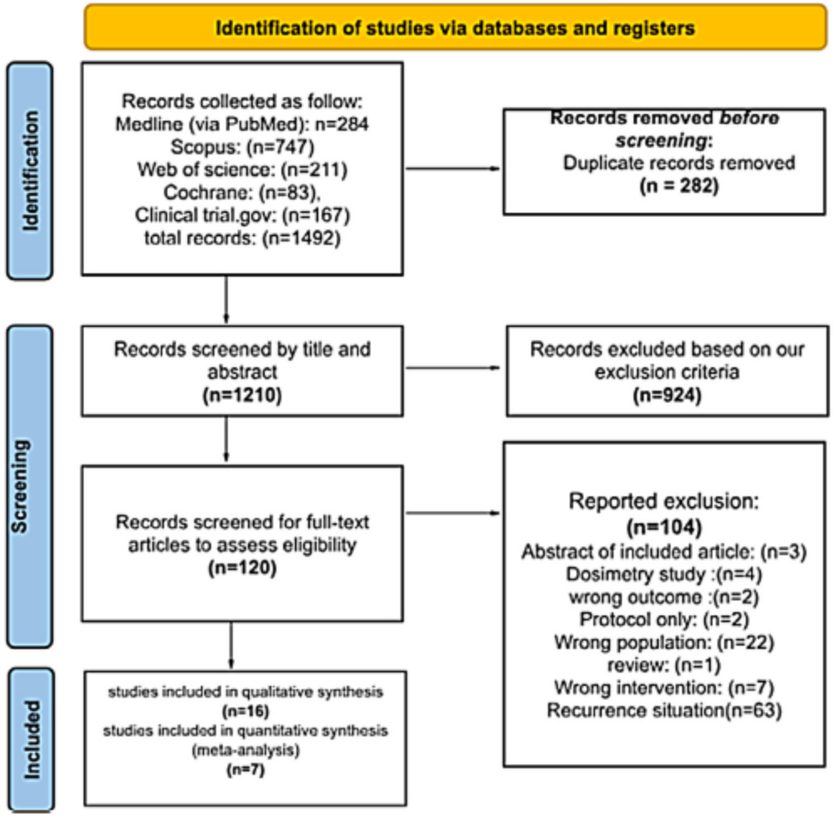
Niazi et al. 2024 – The PCS5 trial directly compares conventional fractionated radiotherapy (CFRT) to moderately hypofractionated radiotherapy (HFRT) with pelvic lymph node radiotherapy (PLNRT) and long-term androgen deprivation therapy exclusively in high-risk prostate cancer patients. Our study demonstrates good survival outcomes, with no significant difference observed between groups in overall survival, prostate cancer–specific survival, biochemical recurrence–free survival, and distant metastasis–free survival between the HFRT and CFRT arms. PTV margins were 5-7 mm on the LN and 10 mm (7 mm post) for the prostate/SV, or 7 mm for centers with OBI or ultrasound targeting.



Safety of Ultrahypofractionated Pelvic Nodal Irradiation in the Definitive Management of Prostate Cancer: Systematic Review and Meta-analysis

Mohamad et al. 2024 – seven publications were included in the meta-analysis, including 417 patients.

- The median total dose to the pelvic lymph nodes was 25 Gy (22.5–28.5 Gy), with a median of 5 fractions.
- The prostate received a median dose of 40 Gy (35–47.5 Gy).
- All studies used androgen deprivation therapy for a median duration of 18 months.
- The rates of acute grade ≥2 GI and GU toxicity were 8% (95% CI, 1%–15%) and 29% (95% CI, 18%–41%), respectively.
- For late grade ≥2 GI and GU toxicity, the rates were 13% (95% CI, 5%–21%) and 29% (95% CI, 17%–42%), respectively.



Osama Mohamad et. al. Safety of Ultrahypofractionated Pelvic Nodal Irradiation in the Definitive Management of Prostate Cancer: Systematic Review and Meta-analysis, International Journal of Radiation Oncology*Biology*Physics, Volume 118, Issue 4, 2024, https://doi.org/10.1016/j.ijrobp.2023.09.053.

Publication (First Author)	CTV_P	CTV_N to PTV_N Margin	CTV_P to PTV_P Margin	Dose to Pelvic Nodes (Gy/Fx)	Dose to Prostate (Gy/Fx, Schedule)	IGRT Technique	Notes
Bauman (FASTR)	Prostate + 1 cm SVs	5 mm	5 mm	25/5	40/5 weekly	CBCT no fiducials	Full bladder/empty rectum required alignment guided by best match of the prostate position with secondary verification of nodal coverage no MRI for contouring no rectal spacer
Glicksman (SATURN)	Prostate only	6 mm	3 mm	25/5	40/5 weekly	CBCT pre&post tx 3 fiducials	Full bladder/empty rectum required MRI not used no rectal spacer
Glicksman (SPARE)	Prostate + SVs	6 mm	0 mm HDR 6 mm EBRT		15 Gy HDR followed (2wk later) by 25/5 weekly	CBCT pre&post tx 3 fiducials	Full bladder/empty rectum (wih enema) required MRI used for contouring no rectal spacer
Glicksman (5STAR)	Prostate only	6 mm	2 mm except 2.5 sup-inf		35/5	CBCT pre&post tx 3 fiducials	Full bladder/empty rectum required Used MRI and urethrogram for contouring used endorectal imobilization system no rectal spacer
Hannan	Prostate + 1 cm SVs (or whole SV if involved)	5 mm	3 mm	22.5–25/5	47.5/5 (36h min between fractions)	CBCT 3 fiducials	Full bladder/empty rectum (with enema) required pelvic bony anatomy was used as surrogate for pelvic nodal field alignment MRI used for contouring all had spacer
Houlihan	Prostate + 1–2 cm SVs	5 mm	5 mm	25/5	36.25–40/5 (weekly)	CBCT 3 fiducials	Full bladder/empty rectum (with enema) required MRI used for contouring all had spacer
Murthy	Prostate +at least 2.2 cm SVs	5 mm	5 mm	25/5	35–37.5/5 (on alternate days)	CBCT no fiducials	Adequate hydration and oral laxative PTV_P was prioritized over PTV_N during manual adjustments MRI used for contouring
Pinitpatcharalert	Prostate + SVs	5–8 mm	5 mm ant-lat 3 mm post 2 mm sup-inf	25/5	37.5–40/5 (on alternate days)	kVs, CBCT 3 fiducials	Full bladder/empty rectum (with enema) required MRI used for contouring Foley placed during CT simulation position based on fiducials and repositioned if bones were off by >0.5 cm, plus intrafraction motion monitoring 22% had spacer
Poon	Prostate + 1 cm SVs	5 mm	5 mm (3 mm post)	25/5	40/5 (twice weekly)	No-fiducials MRI-guided	Treated on MR-LINAC MRI used for contouring used rectal balloons 31% had spacer

- Bauman G, Ferguson M, Lock M, et al. A phase 1/2 trial of brief androgen suppression and stereotactic radiation therapy (FASTR) for high-risk prostate cancer. IntJRadiatOncolBiolPhys2015;92:856-862.
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- Poon D M C, Yuan J,Yang B, et al. A prospective study of stereotactic body radiotherapy (SBRT) with concomitant whole-pelvic radiotherapy (WPRT) for high-risk localized prostate cancer patients using 1.5 Tesla magnetic resonance guidance: The preliminary clinical outcome. Cancers(Basel)2022;14:3484

Pelvic Regional Control With 25Gy in 5 Fractions in Stereotactic Radiation Therapy for High-Risk Prostate Cancer: Pooled Prospective Outcomes From the SHARP Consortium

Murthy et. al. 2024 – SHARP consortium database of patients treated with curative-intent prostate SBRT for high-risk prostate cancer was queried for prophylactic radiation therapy 25Gy/5 to the pelvic lymph nodes. 171 patients were eligible for analysis. Over a median follow-up of 51 months, biochemical failure was recorded for 19(11.1%) patients. Overall pelvic control was 98.2%, with 5-year BFFS and overall survival being 86.1% and 89.3%, respectively.

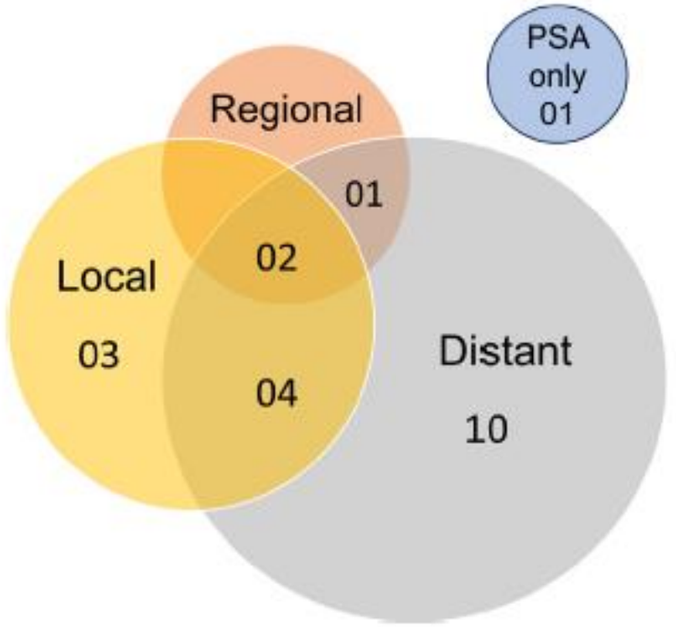
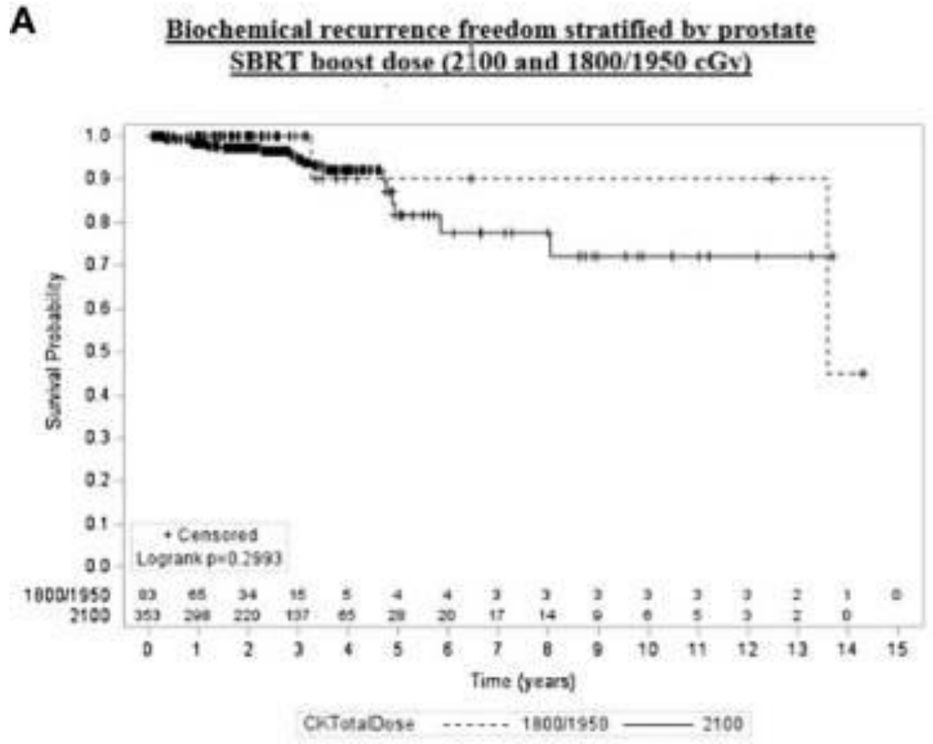


Fig. 1. Patterns of recurrence ($n = 19$).

Murthy, Vedang et al. Pelvic Regional Control With 25 Gy in 5 Fractions in Stereotactic Radiation Therapy for High-Risk Prostate Cancer: Pooled Prospective Outcomes From the SHARP Consortium
International Journal of Radiation Oncology, Biology, Physics, Volume 122, Issue 1, 93 - 98 https://doi.org/10.1016/j.ijrobp.2024.12.018

High-risk prostate cancer treated with a SBRT boost following pelvic nodal irradiation

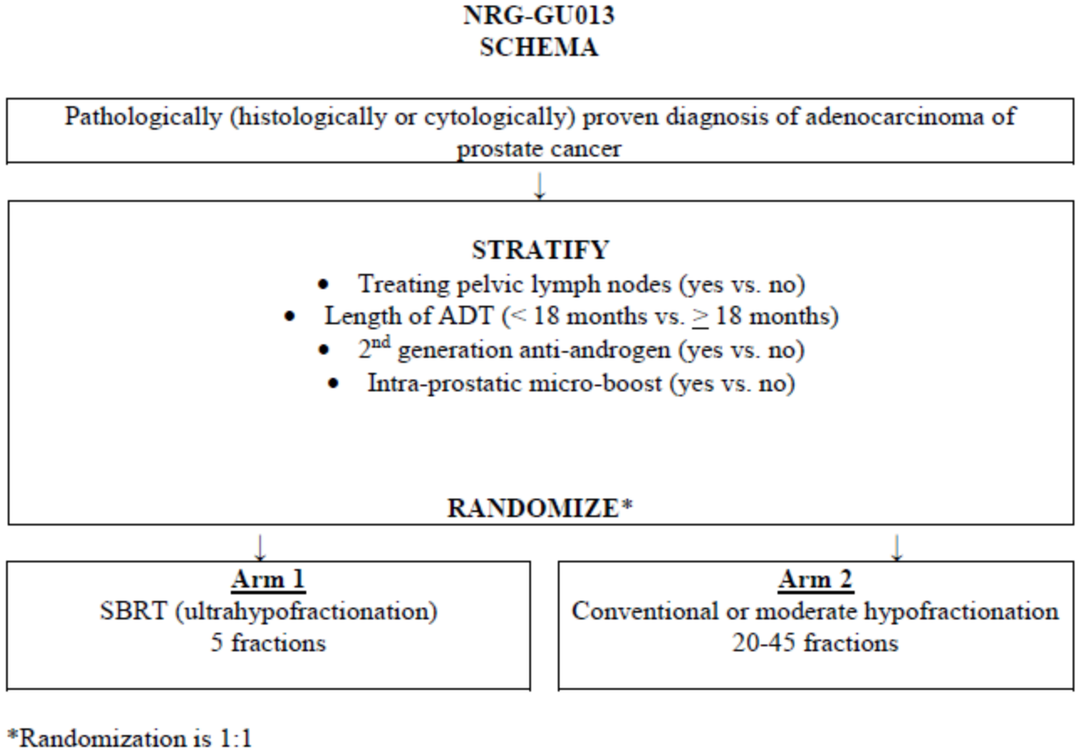
Lischalk et al. 2024 – 440 patients had pelvic nodal irradiation was delivered at a total dose of 4,500 cGy in 25 fractions, followed by a three-fraction SBRT boost of 600-700 cGy. A 5-year freedom from biochemical recurrence (FFBCR) of over 83% with correspondingly limited grade 3+ GU and GI toxicity measured at 3.6% and 1.6%, respectively. Prostate/SV CTV to PTV margins utilized for nodal treatment were 6 mm isometrically. For the SBRT boost portion of treatment, a 5-mm isometric expansion of the CTV with a tighter 3-mm posterior margin was used to create the SBRT PTV.



Lischalk JW, et. al. High-risk prostate cancer treated with a stereotactic body radiation therapy boost following pelvic nodal irradiation. Front Oncol. 2024 Feb 6;14:1325200. doi: 10.3389/fonc.2024.1325200. PMID: 38410097; PMCID: PMC10895712.

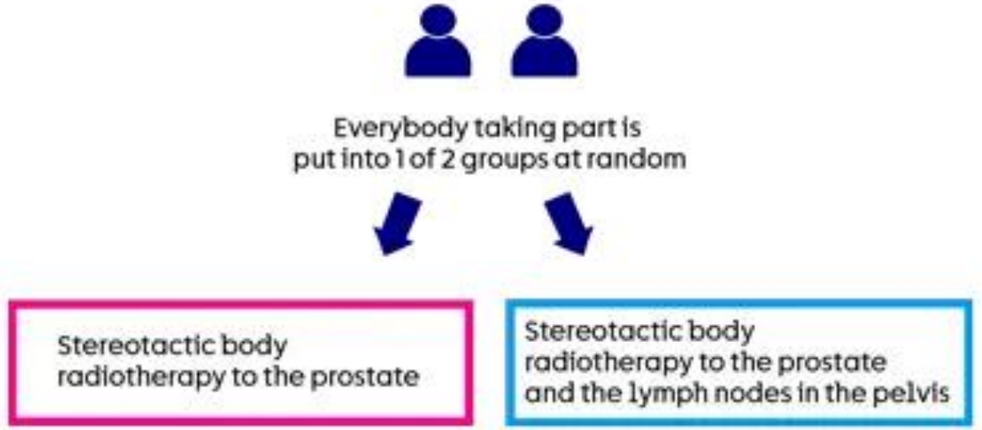
NRG-GU013: THE PHASE III ‘HIGH FIVE TRIAL’ FIVE FRACTION RADIATION FOR HIGH-RISK PROSTATE CANCER

671 patients accrued to date. SBRT arm 40 Gy to the CTV, 36.25 Gy to the PTV margin, 25-30 Gy to uninvolved SV, 25 Gy to the pelvic lymph nodes (included at discretion of treating physician) incases without gross pelvic nodal involvement; pelvic nodal treatment is required in cases with gross pelvic nodal involvement). 30-40 Gy to grossly involved pelvic lymph nodes, where applicable, respecting normal tissue dose-volume criteria.
Required 3 to 5 mm margin on the prostate/SV CTV and 5 to 7 mm on the LN. Daily treatment setup must focus on the prostate, but nodal GTV/CTVs must also be checked.



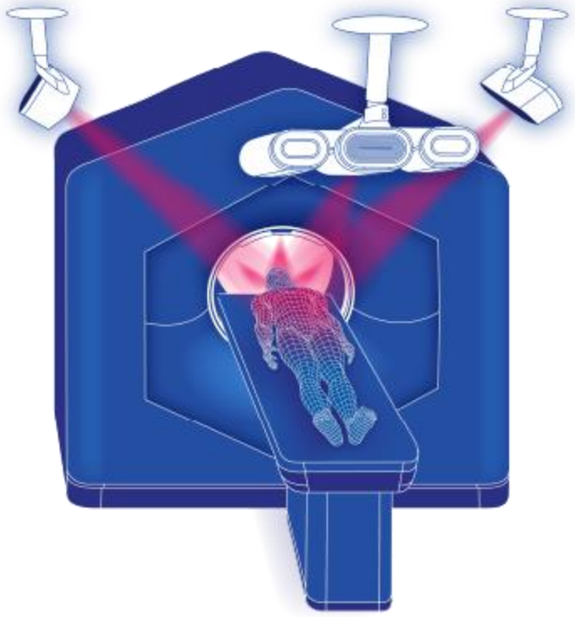
A Trial of 5 Fraction Prostate SBRT Versus 5 Fraction Prostate and Pelvic Nodal SBRT (PACE-NODES)

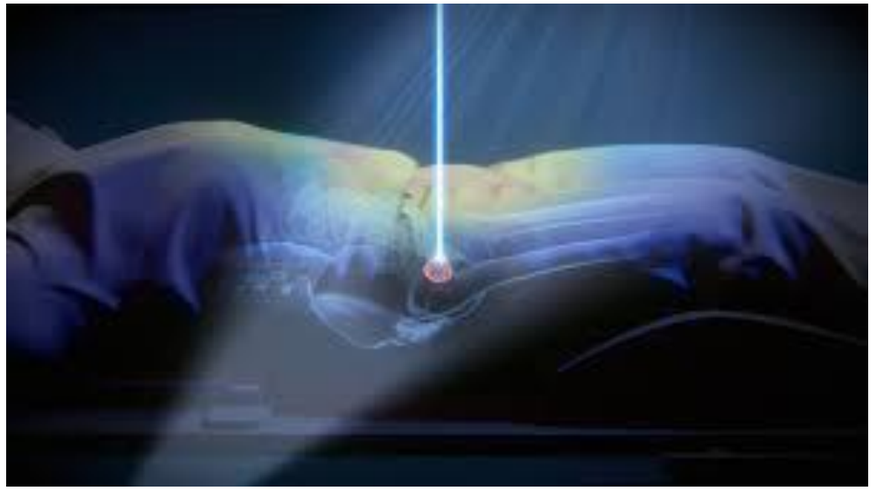
Closed to accrual – planned 1128 participants. Both arms will receive 36.25Gy in 5 fractions to the prostate and seminal vesicles on alternate days (40Gy to prostate clinical target volume (CTV)) with the experimental arm receiving 25Gy in 5 fractions to pelvic nodes on alternate days.



Physics/Clinical Challenges: Treating Nodal Chains or Positive Nodes

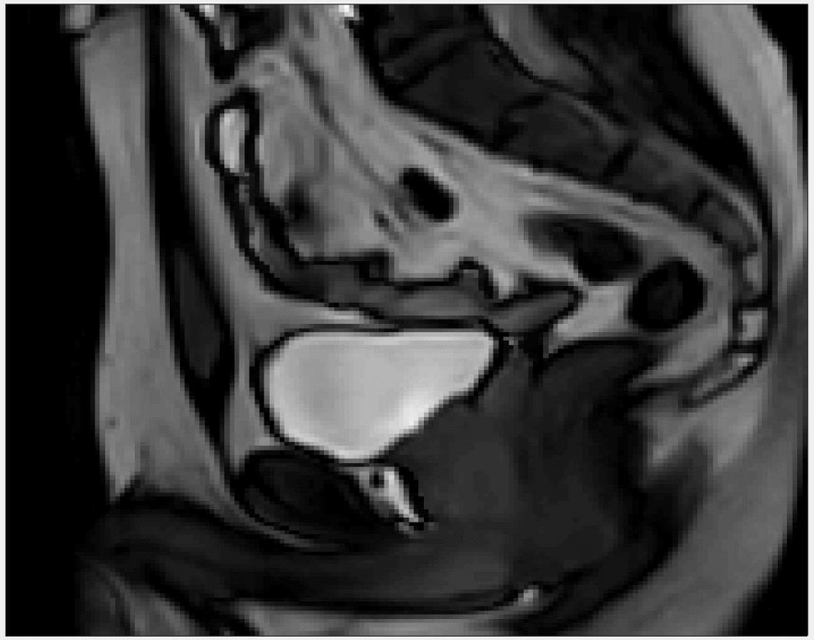
Where treatments include positive pelvic lymph nodes or lymph node chains, extra challenges are presented as there are two distinct targets with different motion profiles.
Lymph node anatomy largely changes with bony anatomy
The prostate & SV exhibit addition motion due to organ filling.
More rigid body frames and/or surface tracking can help minimize bony anatomy changes and gross patient motion over the course of the treatment





Physics/Clinical Challenges: Minimizing Prostate Motion

Care must be taken to ensure patient preparation is consistent for CT and treatment.
A large number of the studies presented used daily enemas or endo-rectal balloons
Patient bladder fill should be consistent.
Treating the CTV to a higher dose whilst maintaining a lower dose to the PTV margin may be more forgiving when prostate motion cannot be compensated for.
Whilst intra-fraction prostate motion monitoring is still beneficial, the question of what to do if/when the prostate moves is more challenging than for prostate only treatments.



Questions for Future Studies/Discussion

- Is treating prostate PTV margins to a lower dose sufficient?
- Will advances in PSMA PET imaging allow for treatment of positive nodes if/when they appear?
- Is there a role for de-escalation of dose to the entire prostate when paired with a boost to the dominant intra-prostatic lesion
- Will online adaptive technologies help in high risk disease?
- Can we separate RT delivery to allow for gating/delivery compensation to only be applied to prostate specific treatment fields
- Would offline summation of delivered dose accounting for plan adaptation allow for more customized dose distributions at subsequent fractions?