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MINI-REVIEW

Stereotactic Body Radiotherapy for Localized Prostate Cancer: A Narrative Mini-Review of Contemporary Evidence

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Abstract

Stereotactic body radiotherapy (SBRT) has evolved from an experimental ultrahypofractionation strategy into a guideline-endorsed standard-of-care option for localized prostate cancer, underpinned by the tumour's low α/β ratio. Level 1 evidence from the PACE-B and HYPO-RT-PC trials establishes five- and seven-fraction regimens as non-inferior to conventionally or moderately hypofractionated radiotherapy in low- and favourable intermediate-risk disease, with comparable long-term toxicity despite a transient increase in genitourinary morbidity. Extension of SBRT to unfavourable intermediate- and high-risk disease, currently being tested in the PACE-C trial and supported by pooled Stereotactic Body Radiotherapy for High-risk Localized Carcinoma of the Prostate (SHARP) consortium data, shows encouraging early efficacy and an acceptable toxicity profile when combined with androgen deprivation therapy, although mature comparative efficacy data remain pending. Technical refinements — particularly magnetic resonance imaging (MRI)-guided delivery with aggressive margin reduction, as demonstrated in the MIRAGE trial — substantially reduce acute and late genitourinary and gastrointestinal toxicity relative to computed tomography-guided delivery. Elective pelvic nodal irradiation using SBRT technique remains investigational pending results of the PACE-NODES trial. Current National Comprehensive Cancer Network, American Urological Association/American Society for Radiation Oncology, and European Society for Radiotherapy and Oncology–Advisory Committee on Radiation Oncology Practice guidance endorses SBRT across risk groups, with continued caution regarding high-risk and nodal applications outside clinical trials. Health-economic analyses consistently favour SBRT over intensity-modulated radiotherapy on cost-effectiveness grounds. This review synthesizes contemporary randomized and pooled-cohort evidence, current guideline recommendations, and emerging technical directions to inform patient selection and treatment delivery for prostate SBRT.

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1. Introduction

Prostate cancer is among the most commonly diagnosed malignancies in men worldwide, and external beam radiotherapy remains a principal curative-intent modality across the risk spectrum. Unlike most solid tumours, prostate adenocarcinoma exhibits an unusually pronounced sensitivity to fraction size, a radiobiological property that has driven a two-decade shift from conventionally fractionated regimens delivered over seven to nine weeks toward

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increasingly hypofractionated schedules.[1,2] Stereotactic body radiotherapy (SBRT) represents the extreme end of this continuum, delivering ablative biologically effective doses in five or fewer fractions over one to two weeks.[3] What began as a pragmatic convenience strategy is now supported by level 1 randomized evidence in low- and favourable intermediate-risk disease and is under active investigation in higher-risk settings.[3–5] This mini-review synthesizes the radiobiological rationale, pivotal randomized and pooled-cohort evidence, toxicity and quality-of-life data, current guideline positions, and emerging technical directions for prostate SBRT.

2. Radiobiological Rationale and Technical Evolution

The rationale for hypofractionating prostate radiotherapy rests on the tumour's low α/β ratio.[1,2] Brenner and Hall first estimated an α/β of approximately 1.5 Gy (95% confidence interval [CI] 0.8–2.2) from clinical outcome data across fractionation schedules.[1] This estimate was independently corroborated by Miralbell and colleagues, who derived α/β = 1.4 Gy (0.9–2.2) from a pooled analysis of 5,969 patients across seven international institutional datasets.[2] Because late-responding normal tissues such as the rectum and bladder have a comparatively higher α/β (approximately 3 Gy), the linear-quadratic model predicts that delivering fewer, larger fractions should favourably widen the therapeutic ratio between tumour control and late toxicity.[1] This radiobiological premise, while influential, is not universally accepted at very large fraction sizes, where the applicability of the linear-quadratic formalism itself has been questioned; nonetheless it has underpinned two decades of hypofractionation and SBRT trial design.[1,2]

Technically, prostate SBRT has been delivered on three principal platforms: robotic, non-coplanar systems with continuous fiducial-based tracking (e.g., CyberKnife); conventional linear accelerators using volumetric modulated arc therapy (VMAT) with daily image guidance; and, more recently, magnetic resonance imaging (MRI)-guided linear accelerators that enable fiducial-free soft-tissue tracking and online adaptive replanning.[3,6] This technical evolution has progressively permitted tighter planning margins and, as discussed in Section 6, measurable reductions in toxicity.

3. Low- and Favourable Intermediate-Risk Disease

The strongest evidence base for prostate SBRT derives from the international, open-label, phase 3 non-inferiority PACE-B trial (ClinicalTrials.gov NCT01584258), which randomized 874 men with low- or favourable intermediate-risk disease (Gleason ≤3+4, prostate-specific antigen [PSA] ≤20 ng/mL, T1–T2, no androgen deprivation therapy [ADT]) at 38 centres in the United Kingdom, Ireland, and Canada to SBRT (36.25 Gy in five fractions over one to two weeks) or control radiotherapy (78 Gy in 39 fractions, or, following protocol amendment, 62 Gy in 20 fractions).[3] Acute toxicity was low and similar between arms.[3] At two years, cumulative Common Terminology Criteria for Adverse Events (CTCAE) grade ≥2 genitourinary (GU) toxicity was higher with SBRT than control (32.3% vs 19.8%; hazard ratio [HR] 1.73, 95% CI 1.32–2.28), whereas Radiation Therapy Oncology Group (RTOG)-scored toxicity was closely similar between arms.[4] The definitive efficacy analysis, at a median follow-up of 73.1 months, demonstrated 5-year freedom from biochemical or clinical failure of 95.7% (95% CI 93.2–97.3) with SBRT versus 94.6% (91.9–96.4) with control radiotherapy, meeting the pre-specified non-inferiority margin (p for non-inferiority = 0.007), with continence and sexual-function patient-reported outcomes broadly comparable between arms at five years.[5]

These randomized findings are reinforced by large pooled prospective cohorts.[6–8] King and colleagues pooled 1,100 patients from eight institutions treated with CyberKnife-delivered SBRT (median dose 36.25 Gy in four to five fractions), reporting a 5-year biochemical relapse-

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free survival of 93% overall (95%, 84%, and 81% for low-, intermediate-, and high-risk disease, respectively).[6] A larger meta-analysis by Jackson and colleagues, incorporating 38 prospective series and 6,116 patients with a median follow-up of 39 months, reported 5- and 7-year biochemical recurrence-free survival of 95.3% and 93.7%, respectively, with late grade ≥3 GU and gastrointestinal (GI) toxicity of 2.0% and 1.1%.[7] Kishan and colleagues similarly reported 7-year cumulative biochemical recurrence rates of 4.5% for low-risk and 10.2% for intermediate-risk disease in a pooled long-term outcomes analysis.[8]

Complementary evidence for ultrahypofractionation comes from the Scandinavian HYPO-RT-PC trial, which randomized 1,200 men (89% intermediate-risk, 11% high-risk, no concurrent ADT) across 12 centres in Sweden and Denmark to 42.7 Gy in seven fractions over 2.5 weeks versus 78 Gy in 39 fractions over eight weeks; notably, 80% of patients were treated with three-dimensional conformal rather than intensity-modulated technique.[9] At five years, failure-free survival was 84% in both arms (adjusted HR 1.002), confirming non-inferiority, with broadly similar patient-reported quality of life through six years despite higher acute toxicity in the experimental arm.[9] Ten-year outcomes, recently reported, confirm durability: failure-free survival of 72% (95% CI 68–76) with ultrahypofractionation versus 65% (61–69) with conventional fractionation (adjusted HR 0.84, 95% CI 0.69–1.03), with similar late toxicity between arms, supporting the seven-fraction schedule as a durable standard-of-care option for intermediate-risk disease.[10]

4. Unfavourable Intermediate- and High-Risk Disease

Randomized evidence in higher-risk disease is less mature.[11] The phase 3 PACE-C trial randomized 1,208 men with intermediate- or high-risk disease (T1c–T3a, Gleason ≤4+4, PSA ≤30 ng/mL), all receiving six to twelve months of ADT, to SBRT (36.25 Gy in five fractions, with a mandated 40 Gy dose to the prostate and proximal seminal vesicles) versus moderately hypofractionated radiotherapy (60 Gy in 20 fractions), across 53 centres in the United Kingdom, Ireland, and New Zealand.[11] Early toxicity findings showed broadly similar co-primary RTOG grade ≥2 GU and GI toxicity between arms despite the larger treated volume relative to PACE-B, although a subsequently reported cumulative CTCAE grade ≥2 GU toxicity signal was again higher with SBRT; the primary efficacy endpoint of freedom from biochemical or clinical failure remains immature at the time of writing.[11]

Pooled data from the SHARP (Stereotactic Body Radiotherapy for High-risk Localized Carcinoma of the Prostate) consortium provide the largest prospective, non-randomized, experience in this population.[12,13] An initial analysis of 344 patients from seven prospective studies (72% receiving ADT, median nine months; median follow-up 49.5 months) reported 4-year biochemical recurrence-free survival of 81.7% (95% CI 77.2–86.5) and distant metastasis-free survival of 89.1% (85.3–93.1), with late grade ≥3 GU and GI toxicity of 2.3% and 0.9%, respectively.[12] An extended analysis pooling ten prospective studies across nine institutions (440 patients; median follow-up 60.4 months), restricting to patients receiving intensified treatment with dose-escalated SBRT (≥8 Gy per fraction) and at least twelve months of ADT, reported 5-year biochemical recurrence and distant metastasis rates of 22% (95% CI 17–26) and 9.2% (6.2–12), respectively, supporting integration of SBRT into shared decision-making for high-risk localized disease pending randomized confirmation.[13] The high-risk subset of HYPO-RT-PC is a further, though limited, data source; these patients did not receive concurrent ADT, which is now standard for definitive radiotherapy in high-risk disease, constraining the generalizability of that cohort to contemporary practice.[9]

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5. Elective Pelvic Nodal Irradiation

Extension of SBRT technique to elective pelvic nodal irradiation in high-risk disease remains investigational. Randomized comparison of prostate-only versus prostate-plus-pelvic-nodal five-fraction SBRT is being conducted in the phase 3 PACE-NODES trial, with recruitment completed and mature efficacy data anticipated in subsequent years. Until these results are available, elective nodal SBRT should be regarded as an area of active clinical investigation rather than a standard treatment option, and its use outside of a trial or registry setting should be approached with caution.

6. MRI-Guided SBRT and Adaptive Radiotherapy

The single-centre, phase 3 MIRAGE trial randomized 156 patients (154 analyzable) to MRI-guided SBRT (2 mm planning margin) versus computed tomography (CT)-guided SBRT (4 mm margin), both delivering 40 Gy in five fractions to the prostate and proximal seminal vesicles.[14] Acute grade ≥2 GU toxicity was significantly lower with MRI guidance (24.4% vs 43.4%; p = 0.01), as was acute grade ≥2 GI toxicity (0.0% vs 10.5%; p = 0.003) with an approximately 60% reduction in the odds of grade ≥2 GU toxicity on multivariable analysis; patient-reported outcomes similarly favoured MRI guidance.[14] These benefits persisted at two years: cumulative late grade ≥2 GU toxicity was 27% with MRI guidance versus 51% with CT guidance (p = 0.0036), and late grade ≥2 GI toxicity was 1.4% versus 9% (p = 0.025), with corresponding reductions in clinically meaningful patient-reported urinary, bowel, and sexual quality-of-life decrements.[15] These findings indicate that the toxicity benefit of aggressive margin reduction, enabled by superior soft-tissue visualization and fiducial-free real-time tracking, is durable beyond the acute treatment period and support MRI guidance as a preferred delivery platform for prostate SBRT where available.[14,15]

7. Toxicity, Quality of Life, and Rectal Spacers

Across the SBRT literature, severe (grade ≥3) toxicity is consistently low, typically under 2–3%, while a measurable excess of moderate (grade ≥2) GU toxicity relative to more protracted fractionation schedules is a recurring signal, particularly on the more sensitive CTCAE scale, as observed in PACE-B and PACE-C.[4,11] GI toxicity is generally comparable between SBRT and fractionated regimens.[4,11] Comparative data against radical prostatectomy are provided by the PACE-A trial, which randomized 123 men with low- to intermediate-risk disease to SBRT (63 patients) or robotic-assisted radical prostatectomy (60 patients); at a median follow-up of 60.7 months, SBRT was associated with substantially lower rates of urinary incontinence (≥1 pad/day at two years: 6.5% vs 50%, p<0.001) and better preserved sexual function (Expanded Prostate Index Composite [EPIC-26] sexual domain score 62.5 vs 18, p<0.001), at the cost of a modestly lower bowel domain score (87.5 vs 100, p<0.001).[16]

Absorbable rectal hydrogel spacers have been evaluated as a toxicity-mitigation strategy.[17] The pivotal multicentre randomized trial by Mariados and colleagues, conducted in the context of conventionally fractionated image-guided intensity-modulated radiotherapy (79.2 Gy in 1.8-Gy fractions; n = 222), demonstrated a significant reduction in late (3–15 month) grade ≥1 rectal toxicity with spacer use (2.0% vs 7.0%; p = 0.04).[17] Evidence specific to the SBRT setting is comparatively limited, and more recent comparative analyses in this context have not uniformly demonstrated a significant toxicity benefit from spacer placement, suggesting that spacer use in prostate SBRT may be more appropriately considered on a selective basis — for example, in patients with anatomically unfavourable rectal proximity or elevated baseline bowel symptoms — pending stronger SBRT-specific randomized data.

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8. Current Guideline Recommendations

The 2018 American Society for Radiation Oncology (ASTRO), American Society of Clinical Oncology (ASCO), and American Urological Association (AUA) evidence-based guideline recommends that ultrahypofractionation may be offered for low- and intermediate-risk disease.[18]

In the 2026 AUA/ASTRO guidelines version, it recommends that moderate hypofractionation should be offered for low- and intermediate-risk disease who elect to receive external beam radiation therapy (EBRT).[19] Ultra hypofractionation may be offered for the same patient population.[19] For patient with high-risk prostate cancer who are candidates for EBRT, clinicians should offer moderate hypofractionated EBRT.[19] The National Comprehensive Cancer Network (NCCN) guidelines for prostate cancer similarly recognize SBRT and ultrahypofractionation as standard-of-care options across risk groups, while treating nodal SBRT more cautiously as an evolving area.[20] At a European level, the European Society for Radiotherapy and Oncology–Advisory Committee on Radiation Oncology Practice (ESTRO-ACROP) has published consensus guidance on image-guided radiotherapy margins and on CT- and MRI-based target-volume delineation for localized prostate cancer, both of which inform the technical execution of SBRT protocols.[21,22]

9. Cost-Effectiveness Considerations

By compressing treatment from up to 39 fractions to five, SBRT offers substantial resource and convenience advantages, which health-economic modelling has consistently translated into favourable cost-effectiveness.[23,24] Sher and colleagues, using a Markov model, reported incremental cost-effectiveness ratios for intensity-modulated radiotherapy (IMRT) over robotic and non-robotic SBRT of $285,000 and $591,100 per quality-adjusted life-year (QALY), respectively, concluding that SBRT contained substantially more value than IMRT across a wide range of sensitivity analyses.[23] Similarly, Hodges and colleagues modelled mean costs and QALYs of $22,152 and 7.9 years for SBRT versus $35,431 and 7.9 years for IMRT, again favouring SBRT provided quality-of-life decrements and efficacy remained within modelled bounds.[24] These analyses collectively support SBRT as a resource-efficient alternative to more protracted external beam regimens, contingent on the assumption of comparable long-term efficacy and toxicity.[23,24]

10. Future Directions

Several developments are likely to shape the future role of prostate SBRT. Focal intraprostatic dose escalation, informed by multiparametric MRI-defined dominant lesions, has demonstrated a biochemical disease-free survival benefit without added toxicity in the randomized phase 3 FLAME trial (77 Gy in 35 fractions to the whole gland, with or without a simultaneous integrated boost to 95 Gy to the dominant lesion), and analogous focal-boost strategies are being explored within SBRT fractionation schedules.[25] Broader hypofractionation evidence, including the individual patient data meta-analysis of moderately hypofractionated regimens conducted within the Multi-institutional Analysis of Radiotherapy for Carcinoma of the Prostate (MARCAP) consortium, continues to refine understanding of dose-response and toxicity relationships across the fractionation spectrum, complementing the SBRT-specific literature summarized above.[26] Mature efficacy outcomes from PACE-C, results of PACE-NODES, and continued follow-up of MRI-guided and adaptive platforms will be pivotal in defining the durable role of SBRT in higher-risk and nodal disease.

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11. Conclusions

Five-fraction SBRT is now supported by level 1 evidence as a standard treatment option for low- and favourable intermediate-risk localized prostate cancer, with durable biochemical control and a toxicity profile that, while associated with a transient increase in genitourinary morbidity, is comparable to conventional and moderately hypofractionated schedules over long-term follow-up. Application to unfavourable intermediate- and high-risk disease is supported by promising but non-definitive pooled cohort data and should, at present, be pursued preferentially within clinical trials or at experienced centres pending mature randomized efficacy data from PACE-C. Technical refinements, particularly MRI-guided delivery with aggressive margin reduction, offer a clear and durable toxicity-mitigation strategy where such platforms are available. Elective nodal SBRT remains investigational. Continued accrual of long-term randomized data, together with ongoing refinement of guideline recommendations, will further clarify the optimal role of SBRT across the risk spectrum of localized prostate cancer.

Declarations

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