

# The Urological Society of India guidelines for the evaluation and management of prostate cancer (executive summary)

These guidelines were drafted by the Urological Society of India Cancer Prostate guideline panel. The authors believe that these guidelines are a guiding framework for a practicing urologist rather than being a rigid clinical pathway and the final treatment should be individualized and should be based on clinical judgment. This is an executive summary of the guidelines with a focus on guideline statements and the complete guidelines can be accessed from the Urological Society of India website at [www.usi.org.in/medical-guidelines](http://www.usi.org.in/medical-guidelines).

## METHODOLOGY

To formulate these guidelines, a literature search was conducted on PubMed, Cochrane Central Register of Controlled Trials, Medley, and Directory of Open Access of Journals. Each set of the search was conducted with a focus on studies generating high-level evidence (randomized trials and systematic reviews) and studies which primarily focussed on the geographical area restricted to "India." Citations from all published English language guidelines and reviews were also searched for relevance. Where ever relevant, other international guidelines were also reviewed. The level of evidence was evaluated by the center for evidence-based medicine method.<sup>[1]</sup> References were collated on the Zotero reference manager and irrelevant and duplicate references were eliminated. Each search was assessed by two individuals with reconciliation of any discordance.

## RECOMMENDATIONS

The guidelines panel made the final recommendations after evaluating the best available global evidence as well as the data from Indian subcontinent. Grades of recommendation (strong/moderate/weak) are the strength of the mandate based on the extent of risk-benefit ratio of either taking or not taking an action. A clinical principle is a statement that is widely agreed upon by clinicians for which there may or may not be evidence in the medical literature. Expert opinion is a statement agreed upon by the guidelines panel in the absence of evidence.

Recent reports from 25 population-based Indian cancer registries show an increase in the incidence of

prostate cancer. This correlates with the recent widespread adaptation of prostate-specific antigen (PSA) screening in the country.<sup>[2]</sup> As per the 2018 GLOBOCAN data, prostate cancer is the sixth most common cancer in the country, with an age-adjusted incidence rate of 10.2/100,000 and age-adjusted mortality rate of 4.2/100,000 population.<sup>[3]</sup>

Prostate cancer, as recorded in the four metropolitan cities, is among the top three cancers diagnosed in men between 2009 and 2011.<sup>[2]</sup> Kolkata has a crude incidence rate of 7.6/100000 population, which is higher than the other three metropolitan cities in the country. However, the age-adjusted rate (ARR) is highest in New Delhi (10.7/100,000 population), followed by Mumbai (7.8), Chennai (7.0), and Kolkata (6.9). Chennai (4.1) had the highest annual percentage change in the age-adjusted incidence rate of prostate cancer, followed by Bengaluru (3.36) and New Delhi (3.33). On the other end of the spectrum, the incidence of prostate cancer is lowest in the north-eastern states of India, followed by Gujarat and Madhya Pradesh.<sup>[2]</sup> The global crude mortality rate of prostate cancer is 9.3/100,000 population, whereas the registered crude mortality rate in India is 4.5/100,000 population for the year 2018 as per the GLOBOCAN data.<sup>[3,4]</sup>

Overall, there is a rising trend in the incidence of prostate cancer globally. The increase in incidence has been projected to be as high as 100.9% in Asian countries including India.<sup>[5]</sup> Similarly, the number of prostate cancer deaths in India is also projected to double by 2040 compared to 2018.

Indian men are diagnosed with prostate cancer at a higher serum PSA level (>10 ng/ml) than their western counterparts.<sup>[6]</sup> They also tend to present with a higher Gleason score ( $\geq 7$ ) at the diagnosis ( $P < 0.001$ ).<sup>[7]</sup> Among Asian Indians who migrate to America, the possibility of finding a pT3 disease and seminal vesicle extension ( $P = 0.03$ ) is significantly greater, although the biochemical recurrence (BCR)-free survival and the positive surgical margin rates are not statistically different from the Caucasians.<sup>[8]</sup> The incidence of metastases is also higher in Indian men than in the western population ( $P < 0.001$ ).<sup>[6]</sup>

## GUIDELINE STATEMENTS

### Screening and early detection

1. Personalized risk stratification may be undertaken for early detection on a case-to-case basis after the age of 50 when the life expectancy is >10–15 years and at-risk

- men must undergo both serum PSA and digital rectal examination (DRE) (strong recommendation).
- No recommendation can be made on the cutoff of PSA values for considering a prostate biopsy. However, a PSA cutoff of 4 ng/ml can be considered for further evaluation (strong recommendation).
  - PSA derivatives should be considered only when the PSA is between 4 and 10 ng/ml (strong recommendation).
  - Multiparametric magnetic resonance imaging (MP-MRI) should be considered only in a patient with elevated PSA and negative DRE (strong recommendation).
  - Age-specific PSA values and PSA density are important concepts to be developed for the Indian setup for screening and early detection as a future direction (strong recommendation).
  - Watchful waiting (WW) can be offered to elderly, asymptomatic men with comorbidities whose life expectancy is <10 years (strong recommendation).
  - Offer radical prostatectomy (RP) to a suitable candidate who understands and accepts long-term oncological outcomes and side effects of the procedure (strong recommendation).
  - Avoid extended pelvic lymph node dissection (ePLND) in low risk disease (LRD) (weak recommendation).
  - Perform nerve-sparing RP with informed patient consent (strong recommendation).
  - Offer radiotherapy (RT) to a suitable candidate who understands and accepts long-term oncological outcomes and side effects of the procedure (strong recommendation).
  - A dose of no less than 74 Gy should be delivered either as a conventional or moderately hypofractionated regimen (strong recommendation).

### **Staging and histology**

- American Joint Committee on Cancer recommends DRE for T staging.
- Contrast-enhanced CT (CECT) or transrectal ultrasound should not be used for local staging (strong recommendation).
- Prebiopsy MPMRI is not recommended for local staging but definitely for pretreatment T-stage assessment (strong recommendation).
- For patients stratified as an intermediate risk with ISUP 3 grade group or high-risk localized cancer prostate, a metastatic workup is recommended (strong recommendation).
- Metastatic workup is best obtained with a prostate-specific membrane antigen (PSMA) positron emission tomography (PET) CECT. Where facilities are not available, clinicians should obtain a bone scan and CECT thorax, abdomen, and pelvis as a means of cross-sectional imaging. A bone scan with <sup>18</sup>F-sodium fluoride PET-CT is superior to the <sup>99m</sup>Tc-methylene diphosphonate (MDP) scan (weak recommendation).
- Histological reporting should follow recommendations by the International Society of Urological Pathology 2014 and the WHO 2016 classification. Apart from the Gleason score, grade grouping is a prognostic pathological indicator (strong recommendation).

### **Treatment of low-risk prostate cancer**

- Active surveillance (AS) can be offered to suitable candidates. Suitability must include the patient's financial condition and access to a health-care facility (strong recommendation).
- Accurate staging includes prebiopsy MPMRI and systemic and targeted biopsies (strong recommendation).
- Follow-up protocol should include DRE, PSA, re-staging biopsy, and MRI as per the clinician's decision (strong recommendation).
- Counsel patients about the possibility of requiring further treatment in future (strong recommendation).

### **Treatment of intermediate-risk prostate cancer**

- Offer AS in selected patients with intermediate risk diseases (IRD) with a clear explanation for the increased chances of metastases (strong recommendation).
- Offer RP with ePLND as a local treatment in IRD (strong recommendation).
- Nerve-sparing RP can be offered if the chances of extracapsular spread are low (strong recommendation).

### **Treatment of high-risk localized prostate cancer**

- RP alone or as a part of a multimodality approach is a reasonable option for high-risk localized prostate cancer (strong recommendation).
- PLND should be part of RP (strong recommendation).
- RT along with long-term androgen deprivation therapy (ADT) is a recommended therapeutic option (strong recommendation).
- Neoadjuvant ADT (androgen deprived therapy) is not recommended before RP (strong recommendation).
- Neoadjuvant ADT for 2–3 months before RT is recommended (strong recommendation).
- Adjuvant ADT after RP is not recommended routinely. It is recommended only in lymph node-positive patients (pN1) (strong recommendation).
- Adjuvant ADT after RT for 2–3 years is recommended (strong recommendation).

### **Treatment of locally advanced prostate cancer**

- RP along with ePLND is a reasonable option for selected patients with locally advanced prostate cancer (LAPC) as part of multimodal therapy (strong recommendation).
- RT along with 2 to 3 years of ADT is a reasonable option for patients with LAPC (strong recommendation).
- ADT monotherapy should only be offered to patients unwilling or unfit for local treatment who are either symptomatic or, have an asymptomatic

- disease with a high or rapidly rising PSA level (strong recommendation).
4. Adjuvant treatment can be considered in men with undetectable postoperative PSA who are at high risk of biochemical relapse (strong recommendation).
  5. Adjuvant ADT should not be offered to patients with N0 disease (strong recommendation).
  6. Adjuvant external beam radiation therapy (EBRT) in the surgical field can be offered to patients who are at increased risk of local relapse: pT3 pN0 with positive margins and/or invasion of the seminal vesicles (strong recommendation).
  7. Patients with pN + disease after an e-PLND can be offered: a. adjuvant ADT (strong recommendation), b. adjuvant ADT with additional RT (strong recommendation), and c. observation if <2 nodes with microscopic involvement, and a PSA <0.1 ng/mL and absence of extranodal extension (strong recommendation).
  8. ADT monotherapy can be deferred in M0 asymptomatic patients unwilling or unfit for any form of local treatment if they have a well-differentiated tumor, a PSA doubling time (PSADT) >12 months, and a PSA <50 ng/mL (strong recommendation).

#### ***Biochemical recurrence after radical prostatectomy or radiation therapy***

1. After RP, a rising serum PSA level is considered a BCR (strong recommendation).
2. After RT, an increase in PSA >2 ng/mL above the nadir, rather than a specific cutoff value, is considered as BCR (strong recommendation).
3. Offer possibly delayed salvage RT (SRT) to patients with BCR who are classified as low-risk of relapse and may not benefit from intervention (strong recommendation).
4. Treat patients with a PSA rise from the undetectable range with SRT. At least 66 Gy of RT should be given as soon as possible after the decision for SRT has been made (strong recommendation).
5. Do not offer hormonal therapy to every pN0 patient treated with SRT (strong recommendation).
6. Offer hormonal therapy (with bicalutamide 150 mg for 2 years, or luteinizing hormone-releasing hormone agonists for up to 2 years) to pN0 patients undergoing SRT (strong recommendation).
7. Do not offer salvage brachytherapy to patients with proven local recurrence as it is still in experimental stages (strong recommendation).
8. Do not offer high-intensity focused ultrasound to patients with proven local recurrence since it is still in experimental stages (strong recommendation).

#### ***First-line therapy in metastatic prostate cancer***

1. ADT should be instituted in all symptomatic men with metastatic hormone-sensitive prostate cancer (mHSPC) (strong recommendation).

2. Do not offer antiandrogen monotherapy (strong recommendation).
3. ADT plus docetaxel therapy should be offered in mHSPC provided the patient is fit to receive the regimen (strong recommendation).
4. Abiraterone plus prednisone in combination with ADT is recommended in the first-line therapy of mHSPC provided the patient is fit to receive the regimen (strong recommendation).
5. Enzalutamide plus ADT is recommended in the first-line therapy of mHSPC provided the patient is fit to receive the regimen (strong recommendation).

#### ***Castrate-resistant prostate cancer***

1. Castrate-resistant prostate cancer (CRPC) is a state with disease progression despite castrate levels of testosterone (clinical principle).
2. Nonmetastatic CRPC patients are diagnosed based on rising PSA in the absence of visible metastasis (clinical principle).
3. Disease progression is defined as any combination of three features – biochemical progression by rising PSA, radiological progression, and clinical progression (clinical principle).
4. Castration is defined as testosterone level <50 ng/ml (moderate recommendation).
5. Biochemical progression is defined as a serial rise in serum PSA level identified with a minimal value of 2.0 ng/ml at least 1 week apart (strong recommendation).
6. Estimations of PSADT with at least three values measured ≥4 weeks apart has prognostic values, especially when PSADT is <10 months in nonmetastatic CRPC setting (moderate recommendation).
7. Conventional imaging using a combination of CT, MRI, and technetium-99m MDP bone scan should be used for baseline radiological assessment and evaluation of treatment response (moderate recommendation).
8. The status of newer molecular scans (like PET scan) remains investigational at present due to a lack of data on improved survival with treatment decisions based on their use (strong recommendation).
9. For patients with metastatic CRPC (mCRPC) following initiation of ADT (with or without additional life-prolonging therapy) appearance of two or more new lesions on the bone scan qualifies as progression (strong recommendation).
10. Soft-tissue progression should be evaluated using response evaluation criteria in solid tumors (RECIST 1.1) (strong recommendation).
11. Any new visceral lesion should be considered as radiological disease progression (strong recommendation).
12. Symptomatic progression in the 1<sup>st</sup> 12 weeks of starting ADT (GnRH agonist) could be due to flare or pseudoprogression and thus radiological evaluation to define progression should be delayed by 12 weeks

- following initiation of such treatment (moderate recommendation).
13. Clinical progression (like significant pain) may precede PSA or radiological progression and demand further evaluation (weak recommendation).
  14. PSA progression and clinical progression in isolation may not mandate a change in therapy without fulfilling one more additional criteria for progression (moderate recommendation).
  15. In nmCRPC patients, 3–6 monthly PSA measurements should be obtained, and PSADT should be calculated beginning from the time of development of CRPC (strong recommendation).
  16. nmCRPC patients should be assessed for the development of metastatic disease using conventional imaging at intervals of 6–12 months (strong recommendation).
  17. In mCRPC patients, clinical evaluation for symptoms and performance status should be performed, laboratory parameters should be obtained, and conventional imaging should be used to confirm the mCRPC status and to assist in the discussion of treatment decision as well as prognosis (strong recommendation).
  18. In patients with mCRPC, germline and somatic tumor genetic testing to identify DNA repair deficiency mutations and microsatellite instability status should be offered (moderate recommendation).
  19. Offer enzalutamide, apalutamide, and darolutamide with continued ADT to nmCRPC patients at high risk for developing the metastatic disease (PSADT  $\leq$  10 months) (strong recommendation) (darolutamide and apalutamide are not available in India).
  20. Secondary hormonal manipulation using abiraterone is an option for those unfit or unwilling for the above-approved drugs (weak recommendation).
  21. Observation with continued ADT may be recommended for nmCRPC patients who are at a lower risk (PSADT  $>$  10 months) of developing the metastatic disease (weak recommendation).
  22. Do not offer systemic chemotherapy or immunotherapy to nmCRPC patients outside the context of a clinical trial (weak recommendation).
  23. Ketoconazole with steroids, first-generation antiandrogens (flutamide, bicalutamide, and nilutamide), estrogen, and estrogen derivatives (fosfestrol) are the other less preferred options in this clinical setting (weak recommendation).
  24. Continue ADT to maintain castrate levels of serum testosterone (strong recommendation).
  25. In newly diagnosed mCRPC patients, offer abiraterone acetate plus prednisone, docetaxel, or enzalutamide along with continued ADT (strong recommendation).
  26. Based on current evidence, it is difficult to recommend one drug over the other as there is a lack of head-to-head comparison in any of the published trials (weak recommendation).
  27. In patients with high visceral metastatic burden and rapid progression on ADT and symptomatic bone metastases, docetaxel may be preferred agent over androgen receptor-targeted agents (ARTA) (moderate recommendation).
  28. Docetaxel should be avoided in patients with poor performance status in view of high risk of adverse effects (strong recommendation).
  29. Both abiraterone and enzalutamide have been found to be effective in chemo-naïve and postchemo clinical settings (strong recommendation).
  30. Low dose abiraterone (250 mg) with fatty meal is noninferior to standard dose abiraterone (1000 mg) and has a definite cost benefit (weak recommendation).
  31. mCRPC patients with AR-V7 positivity have poor response to ART agents (moderate recommendation).
  32. Sipuleucel-T can be offered to asymptomatic and minimally symptomatic mCRPC patients. It may not be justified in the Indian scenario considering the exorbitant cost and minimal improvement in survival and availability of alternative inexpensive drugs (moderate recommendation).
  33. Treatment-emergent neuroendocrine prostate cancer should be suspected in mCRPC patients with rapid clinical and radiographic progression or visceral metastases with low PSA levels (moderate recommendation).
  34. If there is suspicion of dedifferentiation of adenocarcinoma to other histologic variants like neuroendocrine cancer, metastatic lesion biopsy should be considered (strong recommendation).
  35. Neuroendocrine prostate cancers should be treated aggressively with various chemotherapeutic agents and best supportive care (moderate recommendation).
  36. Ablative stereotactic body radiotherapy (SBRT) is recommended for oligoprogression in patients with biologically indolent mCRPC (weak recommendation).
  37. In principle, while sequencing treatments, two drugs with the same mechanism of action should not be offered one after the other— it is advisable to sandwich ART agents with a chemotherapeutic agent (docetaxel/cabazitaxel) whenever feasible (weak recommendation).
  38. While sequencing agents, prior treatment history and recommending therapy with an alternative mechanism of action should be considered (strong recommendation).
  39. While sequencing agents, abiraterone plus prednisolone followed by enzalutamide should be favored over vice-versa as per the Canadian trial (weak recommendation).
  40. In postdocetaxel setting, ART agent is preferred as second-line treatment (moderate recommendation).
  41. In advanced or symptomatic mCRPC patients, cabazitaxel should be recommended as a standard third-line treatment after docetaxel and one ART agent (abiraterone or enzalutamide) rather than an

- alternative ART agent (strong recommendation)
42. In mCRPC patients who received prior docetaxel chemotherapy without prior ARTA for the treatment of CRPC, cabazitaxel can be offered if ART agent is not affordable or available (weak recommendation)
  43. In mCRPC patients, alternative ART agent may be a reasonable option as a third-line drug if they are asymptomatic or had a long-term response to initial ART agent (weak recommendation)
  44. In mCRPC patients, docetaxel rechallenge may be considered in docetaxel responders with a progression-free interval greater than 6 months, if cabazitaxel is not available/tolerable (weak recommendation)
  45. Radium-223 can be offered to patients with symptoms from bony metastases from mCRPC and without known visceral disease or lymphadenopathy >3 cm in the postdocetaxel setting and after using at least one ART agent (strong recommendation) (however, Ra-223 is not available in India)
  46. A PARP inhibitor should be offered to patients with deleterious or suspected deleterious germline or somatic homologous recombination repair gene-mutated mCRPC following prior treatment with ARTA, and/or taxane-based chemotherapy (strong recommendation)
  47. Platinum-based chemotherapy (carboplatin) may be offered as an alternative for patients who 9.49 In patients with mismatch repair deficient or high microsatellite instability mCRPC, pembrolizumab should be offered (moderate recommendation)
  48. The clinician should incorporate multidisciplinary holistic palliative care as an integral part of CRPC management (strong recommendation)
  49. Offer bone protective agents, radiation, or radiopharmaceutical therapeutic options in isolation or combination to patients with mCRPC and skeletal metastases to reduce the risk of SRE and palliate the symptoms (strong recommendation)
  50. A bone-protective agent should be offered (zoledronic acid or denosumab) to patients with mCRPC with bony metastases to prevent skeletal-related events (strong recommendation)
  51. Though denosumab may have a minor advantage over zoledronic acid in terms of preventing SRE and has a safety profile in renal impairment, however, the latter appears more attractive in terms of cost, in the Indian scenario (moderate recommendation)
  52. Optimal scheduling of bone protective agents is not conclusively defined; hence it is recommended to follow the schedule as per trial design (weak recommendation)
  53. The patients should be educated regarding the potential toxicities of bone protective agents and dental examination should be advised before initiation of treatment (strong recommendation)
  54. Calcium monitoring should be started before initiation of treatment with bone protective agents, and calcium and vitamin D repletion as well as continuous supplementation is advised until toxicities appear (moderate recommendation)
  55. Impending spinal cord compression should be managed with immediate high-dose corticosteroids by a multidisciplinary team approach in collaboration with neurosurgeon, orthopedic surgeon, and radiation oncologist (strong recommendation)
  56. EBRT can be recommended to palliate symptoms in patients with severe pain at one or more sites due to bone metastases (moderate recommendation)
  57. Collaboration with nuclear physician should be sought for radiopharmaceutical-based treatment such as Lu-PSMA-617 for palliation of severe bone-related pain (weak recommendation)
  58. PSA-based 3–6 monthly follow-up is advisable in patients with CRPC (strong recommendation)
  59. Routine imaging at 6 months intervals should be a part of nmCRPC follow-up, however in mCRPC imaging should be individualized based on disease progression or annually (weak recommendation).

#### *Emerging modalities and theranostics*

1. Lu PSMA and Ac PSMA have shown promising results in patients with mCRPC (strong recommendation)
2. Lu PSMA can be offered to select patients with mCRPC under clinical trial settings (moderate recommendation)
3. Further trials are required to better establish the role of PSMA-based therapeutic agents and the superiority of one over the other (strong recommendation)
4. Consider germline testing in patients with localized high-risk, locally advanced, and metastatic prostate cancer (weak recommendation).

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