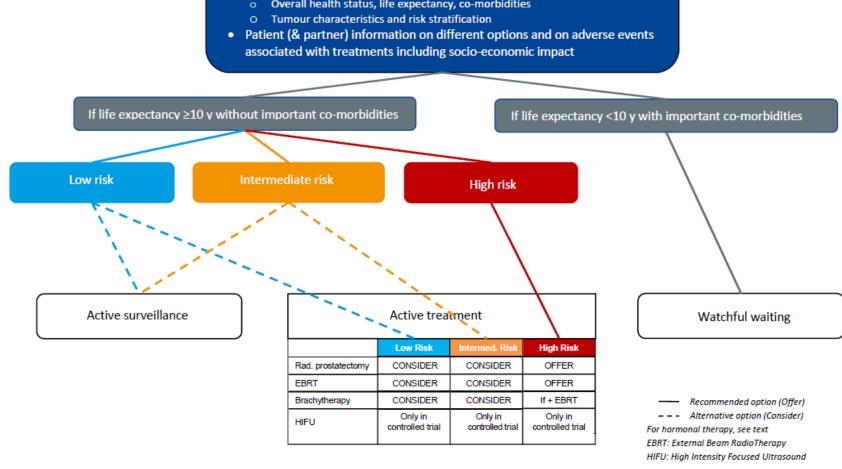
1. ALGORITHM

Diagnosis of localised prostate cancer

- Assessment by a multidisciplinary team:
 - o Urologic assessment in men with urinary symptoms
 - o Overall health status, life expectancy, co-morbidities



Localised Prostate Cancer KCE Report 194 & 226

2. RECOMMENDATIONS

The scientific report with more background information and the methodological approach behind the recommendations can be found in report 194 (link) and in report 226 (link). Some aspects related to cancer treatment are not fully explored (e.g. paramedical interventions). More information on the effectiveness of exercise treatment, pain management and the management of adverse events can be found in reports 185 (link), 211 (link) and 191 (link).

2.1. Patient information

Recommendation	Level of evidence	Strength of recommendation
Before any treatment decision can be made, a assessment should be undertaken during a multidisciplinary team meeting (MDT) including:	NA	GCP
 the patient's overall health status, his individual life expectancy and comorbidities 		
 the quality of the biopsy and tumour characteristics (including the risk category) 		
A patient, eligible and opting for a strategy with curative intent, should be informed about commonly accepted initial managements with regards to his health status, individual life expectancy and tumour risk category. Commonly accepted initial managements include at least active surveillance, radiotherapy (external beam and interstitial), and radical prostatectomy. The estimated benefits and harms of each intervention should be explained and discussed with the patient.	NA	GCP
Prior to prostate cancer treatment, inform men and, if they wish their partner, that any active treatment may result in an alteration of sexual experience and may result in loss of sexual function.	NA	Strong
Inform men and, if they wish, their partner about the potential loss of ejaculation and fertility associated with active treatment for prostate cancer. Discuss the possibility of sperm storage.	NA	Weak
Inform men and if they wish, their partner of the potential effects on urinary function, particularly the risk of incontinence, and digestive function associated with active treatment for prostate cancer.	NA	Strong
Offer a urological assessment to men who experience urinary symptoms before treatment of their prostate cancer.	NA	Strong
Discuss the socio-economical impact of active treatment, including potential professional disability and out-of pocket expenses, related to the management of adverse treatment effects.	NA	Strong

2.2. Watchful waiting

Recommendation	Level of evidence	Strength of recommendation
In patients with localised prostate cancer (all risk category) and individual life expectancy < 10 years or with important comorbidities watchful waiting with palliative intent is recommended.	Moderate	Strong

2.3. Active surveillance

2.3.1. First step

Recommendation	Level of evidence	Strength of recommendation
In patients with low-risk localised prostate cancer, eligible and opting for a strategy with curative intent, active surveillance should be considered as a management option, taking into account patient preferences and health conditions related to urinary, sexual, and bowel function.	Low	Strong
Men with low-risk localised prostate cancer must be informed that at the present time there is no demonstrated benefit within 10 to 12 years for immediate treatments as opposed to observation.	Moderate	Strong
Because of the pathological heterogeneity of the patients with intermediate-risk localised prostate cancer, no general recommendation can currently be made on active surveillance in this subset of patients.	Low	Strong
In patients with high-risk localised prostate cancer, active surveillance is not recommended.	Low	Strong

2.3.2. Active surveillance management

Recommendation	Level of evidence	Strength of recommendation
A repeat biopsy is recommended not later than one year after the diagnosis.	Low	Strong
PSA measurements and clinical examination every six months can be considered. Imaging each year can be considered.	Low	Weak
After the biopsy performed within one year, repeat biopsies are recommended; there timing can currently not be defined.	Low	Strong
In case of the individual life expectancy becomes <10 year or after reaching the age of 80, or in case of the development of significant comorbidity, it is recommended to stop active surveillance and to offer watchful waiting with palliative intent.	Moderate	Strong
Disease progression as suggested by PSA>10ng/mL, or PSADT<3 years, or clinical change, or suspicious lesions at imaging, should be confirmed by an additional biopsy and followed by risk reclassification.	Low	Strong
Switching to a radical treatment should be considered in case of risk reclassification.	NA	GCP

2.4. Active treatment

2.4.1. Radical treatment

Recommendation	Level of evidence	Strength of recommendation
In men with localised prostate cancer to whom active surveillance has been proposed, but who decline, consider standard radical treatment with curative intent (i.e. radical prostatectomy, external beam radiotherapy or brachytherapy).	NA	Weak
In men with intermediate risk localised prostate cancer, consider standard radical treatment with curative intent (i.e. radical prostatectomy, external beam radiotherapy or brachytherapy).	NA	Weak
In men with high risk localised prostate cancer, offer standard radical treatment with curative intent (i.e. radical prostatectomy or external beam radiotherapy).	NA	Strong
Do not offer adjuvant hormonal therapy in addition to radical prostatectomy to men with pN0, even to those with margin-positive disease.	NA	Strong
In men with localised prostate cancer receiving radical external beam radiotherapy with curative intent, offer treatment techniques that optimise the dose to the tumour while minimising the risks of normal tissue damage.	NA	Strong
In men with localised prostate cancer receiving radical external beam radiotherapy with curative intent, offer a minimum dose equivalent to 74 Gy, delivered over 7-8 weeks.	NA	Strong
Do not offer brachytherapy as a unique radiotherapy modality to men with high-risk localised prostate cancer.	NA	Strong
In men with intermediate risk localised prostate cancer treated with radical external beam radiotherapy, consider concomitant androgen deprivation therapy (ADT). Consider to give ADT for 6 months.	Low	Weak
In men with high risk localised prostate cancer treated with radical external beam radiotherapy, offer concomitant androgen deprivation therapy (ADT). ADT should be continued beyond 6 months and for a maximum of 3 years.	Low	Strong

2.4.2. High Intensity Focused Ultrasound (HIFU)

Recommendation	Level of evidence	Strength of recommendation
Consider HIFU as a treatment option in men with localised prostate cancer only in the context of controlled clinical trials.	Very low	Weak



2.4.3. Hormones in mono-therapy

Recommendation	Level of evidence	Strength of recommendation
Do not offer hormonal therapy as a unique treatment modality to men with localised prostate cancer (any risk level).	Moderate	Strong