# Localised prostate cancer

## Immediate treatment, or not: 10-year results

**In a randomised trial including 1643 patients with localised prostate cancer, all detected by PSA screening, the mortality rate after 10 years of follow-up was similar after immediate treatment or after monitoring without initial treatment. Prostatectomy led to an increase in urinary problems and erectile dysfunction.**

In patients with localised prostate cancer, i.e. cancer that does not extend beyond the prostate, the principal therapeutic options are: monitoring without initial treatment, prostatectomy and radiotherapy. The choice mainly depends on the risk of disease progression and on the patient's health status. While the adverse effects of each option are known, comparative assessment of their effectiveness remains insufficient for guiding treatment choice (1). Results of a comparative randomised trial published in 2016 have provided some useful data for providing information to patients (2,3).

**A relevant comparative trial.** The ProtecT trial, started in 1999, compared 3 strategies in 1643 patients aged 50 to 69 years at inclusion: total prostatectomy, versus external beam radiotherapy with androgen-deprivation therapy, versus active monitoring group (2).

All patients had localised prostate cancer detected by PSA (prostate-specific antigen) assay (median concentration at inclusion: 4.6 ng/ml). At enrolment in the trial, the majority of patients had a cancer considered to be at low risk of progression (stage T1 of the TNM classification and a Gleason score of 6) (1,2).

The patients in the active monitoring group had regular measurement of PSA levels during follow-up. In cases of apparent disease progression, the protocol made provision for reassessment in order to make a decision regarding total prostatectomy or radiotherapy, in particular. The primary outcome measure was prostate cancer-specific mortality (2).

**Similar 10-year mortality, irrespective of the initial treatment choice.** At the end of a median follow-up of 10 years, approximately half of the patients in the active monitoring group had not undergone surgery or radiotherapy. The mortality related to prostate cancer was about 1%, with no statistically significant difference between the groups. All-cause mortality was also similar in each group: about 10% (2).

During follow-up, prostate cancer metastases were reported in 6% of patients in the active monitoring group, versus 2% in the surgery group and 3% in the radiotherapy group (p = 0.004) (2).

**Increased frequency of urinary problems or erectile dysfunction after surgery.** The adverse effects of treatment were reported after 6 years of follow-up. There was a statistically significant increase in the frequency of urinary and sexual problems in patients in the surgery group (3).

Six years after randomisation, 17% of patients in the surgery group were using protection to deal with urinary incontinence, versus 4% of patients in the radiotherapy group and 8% of patients in the active monitoring group (3).

Erection was inadequate for sexual intercourse in 83% of patients in the surgery group, versus 73% of patients in the radiotherapy group and 70% in the active monitoring group (3).

Presence of blood in the stool was reported more often by patients in the radiotherapy group than those in the other two groups. Faecal incontinence was reported by 2% to 4% of patients, with no statistically significant differences between the 3 groups (3).

**In practice** In 2017, there is still no evidence that immediate treatment of patients with localised prostate cancer reduces cancer-related mortality as compared to simple monitoring without initial treatment. Total prostatectomy and external beam radiotherapy reduce the risk of metastases, but these treatments are associated with an increase in urinary and sexual problems, and perhaps also intestinal problems with radiotherapy.

This information should be shared with patients in order to support them when making this choice and throughout subsequent monitoring.

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**Selected references from Prescrire's literature search**

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**3-** Donovan JL et al. "Patient-reported outcomes after monitoring, surgery, or radiotherapy for prostate cancer" *N Engl J Med* 2016; **375** (15): 1425-1437.



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