

## Summary and Conclusions

Ultrasound guided tissue sampling (biopsy) is the most common method used to diagnose prostate cancer. While biopsies provide valuable prognostic information, they are limited because it is difficult to be certain that a sample has been taken from the region in the prostate where the potential tumour lies. In addition, patients may find biopsies uncomfortable or even painful. An important question, therefore, is whether more advanced imaging methods can provide more reliable diagnostic information.

This evaluation focuses those men suspected of having prostate cancer based on elevated PSA values, tissue characteristics found during clinical examination, or other reported medical symptoms; and for whom biopsies would be needed to confirm the prostate cancer diagnosis. The imaging techniques evaluated are magnetic resonance imaging (MRI), positron emission tomography with computed tomography (PET/CT), doppler ultrasound, as well as applications of ultrasound techniques such as elastography, where the elasticity of the tissue is measured, and HistoScanning®, where ultrasound information is processed with tissue characterisation algorithms.

### Conclusions

- ▶ Current evidence does not support the routine use of the more advanced diagnostic imaging methods in place of ultrasound-guided tissue sampling when investigating suspected prostate cancer.
- ▶ Higher quality studies are needed to investigate the reliability of diagnostic imaging techniques. This technical information is needed to allow the clinical efficacy of diagnostic imaging techniques to be better assessed in the future.

- ▶ To be able to assess patients' survival and quality of life, as well as the cost-effectiveness of the imaging diagnostic techniques, long-term studies that examine both diagnostic methods and treatments are required.

### Question

What is the diagnostic reliability of imaging methods for suspected prostate cancer?

### Evidence-graded results

The quality of evidence for assessing the diagnostic reliability of various imaging methods compared with ultrasound-guided biopsies for patients with suspected prostate cancer is very low ⊕○○○.

### Ethical aspects

The most frequently used diagnostic method for investigating potential prostate cancer in Sweden is the ultrasound-guided biopsy. However, this method is somewhat unreliable because even if no malignant tissues are discovered, prostate cancer can still not be ruled out, often leading to repeated biopsies. The method also involves risks for the patient, and can be uncomfortable and painful to undergo. If new imaging diagnostic methods prove to be more reliable, these might involve less psychological and physical suffering for the patient. However, there is a risk that if these new methods are introduced for men with suspected prostate cancer, crowding-out effects may occur, because the patient group is large, the methods are relatively costly, and access to equipment and skills is limited.

## Economic aspects

In order to assess whether the use of new imaging diagnostic methods is cost-effective, their costs and effects need to be compared with those of ultrasound-guided biopsies. It is therefore necessary to know how effective the various methods are at detec-

ting prostate cancer in this patient group, something that there is currently insufficient scientific evidence to assess. If there are differences in diagnostic reliability between the methods, it would also be necessary to explore the clinical significance of detecting more cases of cancer.

### Project group

Lennart Blomqvist, Professor,  
Karolinska University Hospital, (Chair)  
Ove Andréén, Associate Professor,  
Örebro University Hospital  
Stefan Carlsson, PhD, Karolinska University Hospital  
Peter Gjertsson, Associate Professor,  
Sahlgrenska University Hospital

### Health Economic Consultants

Martina Lundqvist, Linköping University  
Therese Eriksson, Linköping University

### SBU

Monica Hultcrantz, Project Manager  
Sofia Tranæus, Assistant Project Manager  
Ingegerd Mejåre, Project Manager

Emelie Heintz, Health Economist  
Agneta Brolund, Information Specialist  
Anna Attergren Granath, Project Administrator

### Scientific reviewers

Jonas Hugosson, Professor, Sahlgrenska Academy,  
University of Gothenburg  
Anders Magnusson, Professor,  
Uppsala University Hospital, Uppsala  
Sten Nilsson, Professor, Karolinska University Hospital,  
Stockholm  
Camilla Thellenberg Karlsson, PhD, Norrlands  
Universitetssjukhus

---

SBU Alert report no 2014-01  
www.sbu.se/en • [registrator@sbu.se](mailto:registrator@sbu.se)

**Study quality.** Assessment of to what extent the outcome of an individual study is sensitive to methodological weaknesses. SBU uses only studies with low or moderate risk of bias in the assessment of quality of evidence.

**Strength of evidence.** SBU uses GRADE, an international evidence grading system. Study design is the primary factor considered in the overall appraisal which is performed for each outcome of interest. The quality of evidence is rated down if one or several limitations are present: study limitations, inconsistency of results, imprecision of the estimated result, indirectness of evidence and risk of publication bias. Quality of evidence may also be rated up if there is a strong effect or a dose-response relationship.

The quality of evidence in GRADE has four levels:

- **High quality of evidence** (⊕⊕⊕⊕). Based on studies of high quality with no factors that weaken the overall assessment.

- **Moderate quality of evidence** (⊕⊕⊕○). Based on studies of high or moderate quality with a single factor that weakens the overall assessment.
- **Low quality of evidence** (⊕⊕○○). Based on studies of high or moderate quality with some factors that weaken the overall assessment.
- **Very low quality of evidence** (⊕○○○). SBU considers that when the quality of evidence is very low, it is in practice insufficient. Very low quality of evidence could be due to weaknesses on several areas or that all studies have high risk of bias.

The stronger the quality of evidence, the lower is the likelihood that new research findings would affect the documented results within the foreseeable future.

Conclusions imply an overall assessment of benefits, risks, ethical considerations and cost effectiveness.