Review

Executive summary

Diagnosis, management and screening of early localised prostate cancer

Sara Selley ва Jenny Donovan ва, phd Alex Faulkner ма Joanna Coast ва, мsc David Gillatt FRCs

Department of Social Medicine University of Bristol



Health Technology Assessment NHS R&D HTA Programme

Executive summary

How the research was conducted

• The major databases and bibliographic sources were searched for relevant articles. Using defined selection criteria, 432 key studies were identified.

Research findings

Epidemiology

• The incidence of prostate cancer is increasing worldwide due to the growing elderly population and because a greater number of cases are identified following prostate specific antigen (PSA) testing.

Aetiology

• While age, genetic history and possible diet are risk factors for the disease, further research is necessary.

Diagnostic techniques

- Digital rectal examination (DRE) can be used to detect palpable prostatic tumours, but its sensitivity and specificity are considerably improved when it is used in combination with other techniques. It is not effective as a sole detection method.
- PSA is not a marker solely for prostate cancer, but can be used for the diagnosis of prostate cancer in combination with other techniques and in the follow-up of known cases.
- Transrectal ultrasound (TRUS) is used to estimate the size of the prostate, confirm the diagnosis of palpable tumours and to guide biopsies.
- TRUS-guided biopsy is the "gold standard" for diagnosis.

Staging systems and methods

- The natural history of prostate cancer is poorly understood, but progression appears to be related to stage and grade of the tumour.
- Clinical staging is often unreliable with approximately 50% of all tumours upstaged following surgery.

Treatment

- There is a lack of good quality evidence about the relative effectiveness of the three main treatment options: radical prostatectomy, radiotherapy, and conservative management (monitoring and treatment of symptoms).
- In the absence of high-quality evidence, studies of highly selected patient groups suggest that there may be slightly higher survival rates following radical treatment compared with conservative management. There has, however, been little research into treatment complications and quality of life of men after treatment.

Screening

- Observational studies suggest that DRE and PSA, combined with TRUS and biopsy, can identify localised prostate cancer in 3–5% of men, although false positive and false negative test results will occur.
- Evidence concerning the effectiveness of screening in reducing the number of prostate cancer deaths is very poor.
- Many of the criteria for assessing the need for a population programme have not been met for prostate cancer. In particular, there is a lack of knowledge about the epidemiology and natural history of the disease, a poor level of accuracy in the screening tests, and a lack of good quality evidence concerning the effectiveness and cost-effectiveness of treatments for localised prostate cancer.

Economic issues

• As further clinical evidence is needed about the relative effectiveness of different treatments and the diagnostic techniques, the current economic evidence is poor and does not support population screening.

Main recommendations

• There is no justification for the introduction of population screening.

- PSA testing should be limited to men with clinical evidence of prostate cancer who have a life expectancy > 10 years.
- Serum PSA measurement is recommended for monitoring disease progression.
- The paucity of research evidence suggests that radical treatments should not be performed without the accompanying collection of pre-operative and follow-up data and a co-ordinated programme of audit.
- Conservative management is a reasonable treatment option for men with localised disease, and patients should be informed about the evidence currently available and encouraged to participate fully in decisions about their management.
- There is no justification for the routine use of PSA testing in primary care.

Main research suggestions

• A large-scale randomised controlled trial (RCT) is required to compare radical prostatectomy with conservative management (looking at short and medium term outcomes as well as mortality and progression).

- A full cost-effectiveness analysis is required (i.e. RCT using UK cost data).
- Further research is required into which are the best diagnostic procedures and methods for staging.
- More information is needed about the natural history of prostate cancer, aetiology and risk factors.
- Only when good quality data become available about the natural history of the disease, optimum screening tests and radical treatments, should a full evaluation of the cost-effectiveness of screening be undertaken.

Overall conclusion

• Current evidence does not support a national screening programme for prostate cancer in the UK.

Publication

Selley S, Donovan J, Faulkner A, Coast J, Gillatt D. Diagnosis, management and screening of early localised prostate cancer. *Health Technology Assessment* 1997; **1**(2).

NHS R&D HTA Programme

The overall aim of the NHS R&D Health Technology Assessment (HTA) programme is to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and work in the NHS. Research is undertaken in those areas where the evidence will lead to the greatest benefits to patients, either through improved patient outcomes or the most efficient use of NHS resources.

The Standing Group on Health Technology advises on national priorities for health technology assessment. Six advisory panels assist the Standing Group in identifying and prioritising projects. These priorities are then considered by the HTA Commissioning Board supported by the National Coordinating Centre for HTA (NCCHTA).

This report is one of a series covering acute care, diagnostics and imaging, methodology, pharmaceuticals, population screening, and primary and community care.

A considered decision was taken to commission two similar reports in the area of prostate cancer as an experiment during the initial funding phase of the HTA programme. The aim was to explore the consistency of systematic reviews when commissioned from research teams with different backgrounds and research expertise. This report has, as one of its main focuses, early localised prostate cancer, whereas the related report [Chamberlain J, *et al.* The diagnosis, management, treatment and costs of prostate cancer in England and Wales. *Health Technol Assess* 1997;1(3)] provides a strong link with health economic issues. The two reports provide an excellent overview of this field and will greatly enhance the knowledge base from which future decisions in this field will benefit.

The views expressed in this publication are those of the authors and not necessarily those of the Standing Group, the Commissioning Board, the Panel members or the Department of Health.

Series Editors:Andrew Stevens, Ruairidh Milne and Ken SteinAssistant Editor:Jane Robertson

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The National Coordinating Centre for Health Technology Assessment, Mailpoint 728, Boldrewood, University of Southampton, Southampton, SO16 7PX, UK. Fax: +44 (0) 1703 595 639 Email: hta@soton.ac.uk http://www.soton.ac.uk/~hta