NICE guidance

Transperineal template biopsy and mapping of the prostate

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg364

1 Guidance

1.1 Current evidence on the efficacy of transperineal template biopsy of the prostate shows an increase in diagnostic yield in patients with suspected prostate cancer who have had negative or equivocal results from other biopsy methods. There are no major safety concerns. Therefore this procedure may be used for this indication provided that normal arrangements are in place for clinical governance, consent and audit.

1.2 Evidence was not found to support the use of transperineal template biopsy of the prostate as a mapping technique to determine the exact location and extent of prostate cancer in order to guide focal therapy, nor as part of an active surveillance regime. Therefore the procedure should be used with these intentions only with special arrangements for clinical governance, consent and audit or research.

1.3 Clinicians wishing to undertake transperineal template biopsy of the prostate as part of an active surveillance regime or as a mapping

technique to guide focal therapy of prostate cancer should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients and their carers understand the uncertainty about the use of the procedure for active surveillance and/or mapping, and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended.
- Audit and review clinical outcomes of all patients having transperineal template biopsy of the prostate (see section 3.1).

1.4 NICE encourages further research on the use of transperineal template biopsy of the prostate for both mapping and active surveillance. Comparing the results with specimens obtained at prostatectomy will help to define the accuracy of the procedure in determining the location and extent of prostate cancer.

2 The procedure

2.1 Indications and current treatments

2.1.1 Prostate biopsy in patients with suspected prostate cancer is usually carried out by a transrectal needle biopsy. Amongst other uses, transperineal template biopsy may be used for patients with suspected prostate cancer who have had a negative or inconclusive transrectal biopsy.

2.1.2 The use of transperineal template biopsy of the prostate has also been proposed for other indications including mapping to determine the location and extent of prostate cancer as a guide to focal treatment (such as ablation); as part of active surveillance of low-risk localised prostate cancer with the aim of reducing the number of biopsies; and as a reference test for evaluation of new methods of imaging the prostate.

2.2 Outline of the procedure

2.2.1 This procedure is carried out with the patient under local or general anaesthesia, with intravenous prophylactic antibiotic coverage and a temporary urinary catheter. A grid template with multiple holes approximately 5 mm apart is placed on the perineum. Under transrectal ultrasound guidance a biopsy needle is introduced through different holes in the template, to obtain biopsies from defined parts of the prostate.

2.2.2 Template biopsy allows a large number of tissue samples to be obtained from different parts of the prostate. This may improve detection of small cancers compared with other biopsy methods. An aim of the transperineal approach is to reduce the risk of infection compared with transrectal biopsy.

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview*.*

2.3 Efficacy

2.3.1 A randomised controlled trial (RCT) of 246 patients investigated by 12-core transperineal biopsy or transrectal biopsy reported cancer detection rates of 42% (53/126) and 48% (58/120) respectively ($p = 0.323$). A case series of 373 patients reported that cancer was detected in 76% (60/79) of patients at first biopsy and in 34% (22/64) of patients with 3 or more previous negative biopsies.

2.3.2 A non-randomised controlled study of 135 patients reported greater Gleason score agreement between biopsy and final pathology for 12-core transperineal biopsy (70% [32/46]) compared with 6-core transrectal biopsy (49% [44/89]) ($p = 0.013$).

2.3.3 A case series of 747 patients reported adenocarcinoma detection in 39% (291/747) of patients; more frequently in apical compared with basal regions of the prostate ($p < 0.001$), and anterior rather than posterior regions ($p = 0.036$) (absolute figures not stated).

2.3.4 No evidence was found to support the efficacy of the procedure in active surveillance or for mapping as a guide to focal prostate cancer therapy.

2.3.5 The Specialist Advisers listed key efficacy outcomes as prostate cancer detection rate (particularly apical tumours) and better tumour localisation.

2.4 Safety

2.4.1 The RCT of 246 patients biopsied by either a transperineal or transrectal approach reported fever greater than 38.5°C in 0% (0/126) and 2% (2/120) of patients respectively (p = 0.136). Infection (not otherwise described) was reported in 1 patient in the case series of 747 patients (follow-up not stated).

2.4.2 The RCT of 246 patients investigated by transperineal or transrectal prostate biopsy reported haematospermia in 2% (2/126) and 0% (0/120) of patients respectively (p = 0.166) (duration and follow-up not stated).

2.4.3 Urinary retention was reported in 10% (77/747) (all required a catheter when discharged from hospital), 2% (6/371) (all required overnight catheterisation), 2% (7/303) (not otherwise described) and 11% (24/210) (not otherwise described) of patients in case series of 747, 371, 303 and 210 patients.

2.4.4 The Specialist Advisers considered theoretical adverse events to include septicaemia, bleeding, urinary tract infection and haematuria.

2.5 Other comments

2.5.1 The Committee noted that there is considerable variation in the number of biopsy samples taken during the procedure.

3 Further information

3.1 This guidance requires that clinicians undertaking the procedure as part of an active surveillance regime or as a mapping technique to guide focal

prostate cancer therapy make special arrangements for audit. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion).

3.2 For related NICE guidance see our website.

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind. A large print version is also available.

4 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

We have produced a summary of this guidance for patients and carers. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Changes since publication

3 January 2012: minor maintenance.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however,

override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation