NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Health Technology Appraisal

Intensity modulated radiotherapy for treatment of prostate cancer

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of intensity modulated radiotherapy for the treatment of prostate cancer.

Background

The prostrate is a gland found only in men and is situated in the pelvis. The function of the prostate is to produce and store seminal fluid. Prostate cancer is the most common cancer in men. In England and Wales, there were over 31,000 cases of prostate cancer in 2004, and over 9,000 deaths due to prostate cancer in 2005. Very many more men have prostate cancer than are ever diagnosed or develop symptoms of the disease. The incidence of prostate cancer increases with age and the majority of men have histological evidence of prostatic cancer by age 80 but are more likely to die of unrelated causes.

Prostate cancer may be diagnosed following the onset of symptoms or may be detected following routine screening of men by measurement of Prostate-specific antigen (PSA) and digital rectal examination (DRE). Treatment at detection depends on the age, condition and life expectancy of the sufferer. It is also determined by the stage (spread) and the grade of the tumour. Patient preference and willingness to accept the side effects of treatments are important considerations for the choice of treatment.

For tumours localised to the gland the attempt is to effect a cure with radical surgery. However, radiotherapy is also considered to be an effective option for localised disease. Radiotherapy is usually offered as the primary treatment to patients with locally advanced disease that has spread beyond the capsule of the prostate. Radiotherapy is also useful in managing metastatic disease, especially in bone, and in controlling the pain that is associated with metastatic disease.

Currently radiotherapy is delivered using 3-dimensional conformal radiotherapy (3D CRT). It is delivered by non-modulated beams, which can be shaped geometrically to avoid irradiating normal surrounding tissue. Side effects of radiation include cystitis, haematuria, urinary stricture and incontinence, proctitis, chronic diarrhoea and leg oedema.

The technology

Intensity modulated radiotherapy (IMRT) is the term applied to any radiotherapy where the beam of radiation is not uniform across the field to be

irradiated, but consists of beamlets of varying intensity. IMRT is delivered by attaching a multileaf collimator (MLC) to a linear accelerator or by using compensators which are designed and constructed for individual patients. The modulation of the radiation beam in IMRT allows precise delivery to cancerous tissue while sparing surrounding normal tissue from exposure. It is therefore suitable for the delivery of radiation to locations where diseased tissue is located close to vital structures and decreases the side effects of radiation.

IMRT systems available in the UK include the following models:

Manufacturer	Model
Elekta	Axesse Precise Treatment System Synergy Synergy Platform
Varian	Clinac Trilogy
Siemens	Artiste Primus Oncor Impression Oncor Avant-garde Oncor Expression Simtec
TomoTherapy	Hi-Art

The system requires essential software that allows the physician to determine the dose and distribution of radiation. IMRT makes use of 'inverse planning' where the clinician determines the dose and distribution of radiation and computer software works backwards from this to determine the direction and intensity of the beams required to achieve this. IMRT can also be delivered using 'forward planning'.

Systems that combine the ability to simultaneously image can improve the accuracy of targeting of radiation by compensating for movement of body structures. Imaging also allows verification of the actual dose delivered and allows for compensation for any deviation from planned dose in subsequent sessions.

Quality assurance (QA) is an important component of IMRT. It consists of checks on the precision of the equipment and verification that the prescribed dose and dose distribution have been planned and are being delivered. For some cancers QA is less time consuming as the QA procedure can be standardised for the class of tumour, but for unusual or complex cancers it needs to be individualised.

Intervention	Intensity modulated radiotherapy
Population(s)	Men with prostate cancer for whom radiotherapy is appropriate.
Standard comparators	3-dimensional conformal radiotherapy (conventional radiotherapy) Radical prostatectomy
Outcomes	The outcome measures to be considered include: • overall survival • progression-free survival • response rates • adverse effects of treatment • health-related quality of life • prostate-specific antigen
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective. This should include costs for specialist staff and quality assurance.
Other considerations	If evidence allows, the appraisal will seek to identify subgroups of individuals for whom the technology is particularly clinically and cost- effective. Possible subgroups could be based on the stage of the cancer, prognostic risk groups, the use of neoadjuvant hormonal therapy or the need for pelvic lymph node radiotherapy.

Related NICE recommendations	Related Technology Appraisals: Technology Appraisal guidance No.101 - Docetaxel for the treatment of hormone refractory prostate cancer. June 2006. Related Guidelines: Guidance on Cancer Services, improving outcomes for urological cancers, Sept 2002. CG 58. Prostate Cancer: diagnosis and treatment. February 2008. Interventional Procedures: Interventional Procedures Guidance IPG 193 - Laparoscopic radical prostatectomy. November 2006 Interventional Procedures Guidance IPG 174 - High dose rate brachytherapy for prostate cancer. May 2006. Interventional Procedures Guidance IPG 145 - Cryotherapy as a primary treatment for prostate cancer. November 2005 Interventional Procedures Guidance IPG 132 - Low dose rate brachytherapy for localised prostate cancer July 2005 Interventional Procedures Guidance IPG 119 - Cryotherapy for recurrent prostate cancer. May 2005. Interventional Procedures Guidance IPG 118 - High-intensity focused ultrasound for prostate cancer. March 2005.