

Advice Statement

¹⁸F-fluorodeoxyglucose (FDG) positron emission tomography – computed tomography (PET-CT) for routine staging and monitoring of treatment response in patients with anal cancer



Advice for NHSScotland

In primary tumour staging in patients diagnosed with anal cancer, FDG PET-CT should be considered as an adjunct to clinical assessment and magnetic resonance imaging (MRI) or computed tomography (CT) imaging.

For radiotherapy treatment planning in patients with anal cancer, FDG PET-CT should be considered as an adjunct to clinical assessment and MRI or CT imaging.

It is not possible to provide advice on the use of FDG PET-CT for monitoring of treatment response in patients with anal cancer due to a lack of studies assessing this outcome.

There is uncertainty about the balance of costs and benefits of FDG PET-CT for anal cancer due to a lack of published cost effectiveness studies. Cost data for FDG PET-CT in Scotland should be collected in future to inform further assessments on this technology.

NHSScotland is required to consider the Scottish Health Technologies Group (SHTG) advice.

Why is SHTG looking at this topic?

The Scottish Clinical Imaging Network (SCIN) working group on PET-CT produce recommendations on the use of this technology in NHSScotland. An evidence review on effectiveness of FDG PET-CT in patients with anal cancer will support the SCIN group to formulate recommendations for this patient population. The topic was prioritised for inclusion on the SHTG work programme following a topic referral from the SCIN working group on PET-CT.

Evidence Note 90 was produced by Healthcare Improvement Scotland in response to this request.

Background

Anal cancer is a relatively rare cancer, accounting for less than 1% of all new cancer diagnoses in the UK. In 2014-15 there were 143 new cases of anal cancer diagnosed in Scotland. Anal cancer affects approximately twice as many women compared with men and incidence increases with age.

Accurate staging of the primary tumour and lymph nodes is important for selecting the most appropriate treatment for anal cancer and for planning subsequent radiation therapy. In particular, volumetric arc therapy (VMAT) can be used to differentially allocate radiation doses to specific targets based on accurate staging.

Routine staging of anal cancer currently involves a detailed clinical assessment, magnetic resonance imaging (MRI) of the pelvis and computed tomography (CT) of the chest, abdomen and pelvis. ¹⁸F-fluorodeoxyglucose (FDG) positron emission tomography-computed tomography (PET-CT) could potentially be used as an addition to the current diagnostic process for primary tumour staging, lymph node staging, radiotherapy planning, or assessment of treatment response in patients with anal cancer. All the evidence reviewed was for FDG PET-CT, which has been abbreviated to PET-CT for the purposes of this Advice Statement.

Clinical effectiveness

Diagnostic accuracy

- The evidence on PET-CT in patients with anal cancer consisted of four systematic reviews with meta-analyses of mainly retrospective non-randomised diagnostic studies. There was a high degree of overlap of studies included in these reviews. The quality of included studies was interpreted differently in each review, although all noted a risk of bias from unblinded interpretation of images.
- Two meta-analyses reported PET-CT had a sensitivity of 99% (95% confidence interval (CI) 96% to 100%, 10 studies, n=381 and 95% CI 97% to 100%, 8 studies, n=428) indicating a low false negative rate for detection of the primary tumour in patients with anal cancer compared with a histology reference standard. Specificity was not reported in either meta-analysis, therefore the false positive rate is unknown.
- One meta-analysis (2 studies, n=148) reported a per-patient sensitivity of 93% (95% CI 76% to 99%) and specificity of 76% (95% CI 61% to 87%) for PET-CT detection of inguinal lymph node involvement. In a per-lesion meta-analysis (6 studies) PET-CT had a sensitivity of 56% (95% CI 45% to 67%) and specificity of 90% (95% CI 86% to 93%) for detection of locoregional lymph node involvement.

Impact on treatment

- Studies included in a systematic review (11 studies, median n=46) reported upstaging for 5.1% to 37.5% of patients and downstaging for 8.2% to 26.7% of patients. In a meta-analysis (10 studies, n=381) PET-CT resulted in a nodal upstaging rate of 21% (95% CI 13% to 30%) and downstaging rate of 17% (95% CI 11% to 23%).

- In one meta-analysis (6 studies, n=284) PET-CT identified distant metastases of anal cancer which had been missed on conventional imaging in an estimated 3% (95% CI 1% to 5%) of patients. Not all stage changes were verified using biopsy.
- Radiotherapy target volume definition changed following PET-CT imaging in an estimated 23% (95% CI 18% to 29%) of patients compared with CT alone (9 studies, n=274).
- Based on PET-CT imaging patient treatment plans were modified for 12.5% to 59.3% of patients (8 studies, n=423); lymph node treatment increased in 15% of patients and decreased in 9% of patients (5 studies, n=129); and treatment intent changed from curative to palliative in 3% (95% CI 2% to 6%) of patients (10 studies, n=394).
- A single study (n=40) evaluated using PET-CT for assessing treatment response in patients with anal cancer at one and three months after treatment. This study may have attempted to measure treatment response too soon after treatment to reliably estimate effectiveness.

Safety

- No adverse events relating to PET-CT in patients with anal cancer were reported in the systematic reviews.
- Undergoing a PET-CT scan represents an additional radiation burden for patients compared to CT alone. A PET-CT scan exposes patients to a radiation dose equivalent to 8 years of natural radiation exposure, for example from the sun, while a basic CT scan exposes patients to the equivalent of 3 years natural radiation.

Cost effectiveness

- No cost-effectiveness evidence was identified relating to the use of PET-CT in patients with anal cancer.

Further research

Current evidence on PET-CT in patients with anal cancer appears to be at stage three or four of the [IDEAL-D framework](#). Future studies should be controlled, blinded, diagnostic studies, and economic evaluations.

- Studies are required that assess the impact of PET-CT on clinical outcomes in patients with anal cancer.
- Diagnostic studies are needed to evaluate the effectiveness of PET-CT for assessing treatment response in patients with anal cancer.
- Economic analyses are required to evaluate PET-CT in patients with anal cancer.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full. This advice represents the view of the SHTG at the date noted.

It is provided to inform NHS boards in Scotland when determining the place of health technologies for local use. The content of this Advice Statement was based upon the evidence and factors available at the time of publication. An international evidence base is reviewed and thus its generalisability to NHSScotland should be considered by those using this advice to plan services. It is acknowledged that the evidence constitutes only one of the sources needed for decision making and planning in NHSScotland. Readers are asked to consider that new trials and technologies may have emerged since first publication and the evidence presented may no longer be current. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgment in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

SHTG Advice Statements will be considered for review if new evidence becomes available which is likely to materially change the advice. Stakeholders may submit a request, highlighting new evidence to shtg.hcis@nhs.net

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Chair

Scottish Health Technologies Group



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