Is FDG PET-CT clinically and cost-effective in the staging and/or restaging of disease in patients with penile or testicular cancers?

This advice has been produced following completion of evidence note 73 by Healthcare Improvement Scotland, in response to an enquiry from the Scottish PET-CT Working Group. The evidence note is available from the Healthcare Improvement website.

Background

- Penile cancer is rare in developed countries and there are typically fewer than 100 people diagnosed with this disease every year in Scotland. Testicular cancer is relatively more common, and will lead to approximately 200 people being newly diagnosed in Scotland each year.

- In both penile and testicular cancers, conventional CT imaging has been recommended at specified points during the staging and/or restaging process. $^{18}$F-2-fluoro-2-deoxy-D-glucose (FDG) is a radioisotope given to patients prior to PET-CT hybrid imaging. The resulting images could potentially enhance the information yielded by current imaging techniques and other diagnostic information used to inform staging and/or restaging.

- The reference standard for staging and/or restaging penile and testicular cancers includes CT but is not CT alone, so it was not possible to directly compare FDG PET-CT and CT.

Clinical effectiveness

- There were a small number of studies identified for each cancer, and sample sizes were relatively small. There was heterogeneity in the comparisons being made and poor reporting of separate staging and restaging results.

- For both penile and testicular cancers, current clinical practice in Scotland involves contrast enhanced CT imaging. It is not clear how accurately CT performed in the identified studies reflects CT as used in clinical practice in Scotland, as none of the included studies were conducted in Scotland and only one was UK-based.

Penile Cancer

- One systematic review was identified containing seven studies (of which four were relevant primary studies, two were conference abstracts and one was a case series of three patients). From 213 images, the pooled sensitivity and specificity were 0.81 (95% CI 0.70 to 0.89) and 0.92 (95% CI 0.87 to 0.96) respectively.

- In one of two more recent primary studies identified, sensitivity (0.91) exceeded the upper limit of the 95% confidence interval (CI) of the pooled sensitivity from the review.
Only one (non UK-based) study, reported patient management outcomes gathered from a survey of clinicians. This showed, after adjusting for management changes that would have occurred using CT imaging, in 18 of 44 cases (40.9%) the FDG PET-CT results influenced the management of patients.

**Testicular Cancer**
- One systematic review was identified, but only two of the nine included studies assessed the intervention of interest (FDG PET-CT rather than FDG PET alone). From 375 images, pooled sensitivity was 0.78 (95% CI 0.67 to 0.87) and pooled specificity was 0.86 (95% CI 0.81 to 0.89).
- Five additional primary studies were identified. Sensitivity exceeded the upper limit of the 95% CI for the pooled review data in three studies (with rates of 0.89, 0.93 and 0.94 respectively), as did specificity in two studies (with rates of 0.90 and 0.97), although specificity was lower in another study (0.75).
- One (non-UK based) study reported a change in clinical management based on the addition of FDG PET-CT in 106 of 121 (82.1%) images, but this was not adjusted to account for any change in patient management that would have occurred based on the findings of CT alone.

**Safety**
- The identified studies did not evaluate any adverse events or effects relating to the use of FDG PET-CT.
- Imaging using FDG PET-CT involves exposing patients to ionising radiation, and guidelines have noted this to be a particular concern for testicular cancer patients due to prognostic trends for this disease.

**Cost effectiveness**
- None of the identified studies reported data on cost-effectiveness.

**Conclusion**
- There is insufficient evidence on the clinical and cost-effectiveness of FDG PET-CT and none of the identified studies reported any long-term oncological or quality of life outcomes resulting from changes in patient management.
- It is not currently possible to draw any conclusions on the effectiveness for staging and/or restaging of patients with penile or testicular cancers in the NHS in Scotland.
- Current evidence on FDG PET-CT for penile or testicular cancer patients appears to be at stage 2 or 3 of the IDEAL-D framework. Future studies should therefore be prospective, blind, controlled, diagnostic studies, or economic evaluations.

**Advice context:**

*The status of SHTG Advice Statements is ‘required to consider’.*

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. SHTG Advice Statements are intended to inform a decision at a particular point in time. They will however be considered for review if...
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Chair
Scottish Health Technologies Group

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