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Recommendation Report PET #12

The Clinical Utility of Positron Emission Tomography in the Diagnosis, Staging, and Clinical Management of Patients with Lymphoma: Recommendation Report

C.T. Kouroukis, M. Cheung, J. Sussman, D. Hodgson, M. Freeman and S. Kellett

A Quality Initiative of the
Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO)

Report Date: March 13, 2015

Evidence-Based Series PET #12 is comprised of 2 sections:	
Section 1:	Guideline Recommendations
Section 2:	Evidentiary Base

For further information about this report, please contact:

Sarah Kellett
Health Research Methodologist, Program in Evidence Based Care
Juravinski Hospital, G-Wing, Second Floor, Room 221
711 Concession Street, Hamilton, Ontario, L8V 1C3
Phone: 905-527-4322 ext. 42854 Fax: 905-526-6775 Email: kellett@mcmaster.ca

Dr. C. Tom Kouroukis
Associate Professor, McMaster University, Department of Oncology
Division Head, Malignant Hematology, Juravinski Cancer Centre, 3rd Floor
699 Concession Street, Hamilton Ontario, L8V 5C2
Phone: 905-387-9711 ext. 62487 Fax: 905-575-6340 E-mail: tom.kouroukis@jcc.hhsc.ca

For information about the PEBC and the most current version of all reports, please visit the CCO Web site at http://www.cancercare.on.ca/ or contact the PEBC office at:
Phone: 905-527-4322 ext. 42822 Fax: 905 526-6775 E-mail: ccopgi@mcmaster.ca

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Recommendation Report PET #12: Section 1

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QUESTIONS

DIAGNOSIS AND STAGING

What benefit to clinical management does ^{18}F-fluorodeoxyglucose (FDG) positron emission tomography/computed tomography (PET/CT) contribute to the initial diagnosis or staging of lymphoma?

DIAGNOSIS OF RECURRENCE AND ROUTINE FOLLOW-UP

What benefit to clinical management does FDG PET/CT contribute after conventional imaging is performed, in patients with suspected or proven recurrence of lymphoma? What benefit to clinical management does FDG PET/CT contribute to routine follow-up at the time of documented recurrence for lymphoma?

RESPONSE EVALUATION (interim and at completion of therapy)

What benefit to clinical management does FDG PET/CT contribute to the interim assessment of treatment response and assessment of residual mass for lymphoma?

TARGET POPULATION

The target population for these recommendations is adult patients suspected of, with a diagnosis of, or recurrence of lymphoma including Hodgkin lymphoma (HL) and non-Hodgkin lymphoma (NHL).

INTENDED USERS

- This recommendation report is intended to guide the Ontario PET Steering Committee in their decision making concerning indications for the use of PET imaging.

- This recommendation report may also be useful in informing clinical decision making regarding the appropriate role of PET imaging and in guiding priorities for future PET imaging research.

RECOMMENDATIONS AND KEY EVIDENCE

These recommendations are based on an evidentiary foundation of one high-quality United Kingdom (UK) Health Technology Assessment (HTA) that included systematic review and primary study literature for the period from 2000 to August 2005 (1). An update of this systematic review was undertaken by the New Zealand Guidelines Group (NZGG) to retrieve the evidence from the period from August 2005 to November 2011 (2). The Program in Evidence-Based Care (PEBC) has endorsed and adapted this evidentiary base for the purpose of this recommendation report; however, 17 additional studies were added post hoc by the PEBC team due to differences in the research objectives of the NZGG and the PEBC. In the NZGG report, systematic reviews were included. This PEBC review did not include these systematic reviews due to overlap in the studies between the reviews; however, the references lists of these systematic reviews were checked to ensure that no primary studies were missed. From this point forward in this document, reference will only be made to the UK HTA (primary studies prior to August 2005) and the primary studies included in this recommendation report (primary studies from August 2005 to November 2011). Pediatric studies were included in the systematic review and qualitatively summarized in Section 2 of this report; however, they were not utilized as part of the evidentiary base for these recommendations.

RECOMMENDATIONS AND KEY EVIDENCE
Diagnosis

Recommendation(s):
A recommendation cannot be made for or against the use of FDG PET/CT for the diagnosis of lymphoma due to insufficient evidence.

***Key Evidence*:**
UK HTA (studies published prior to August 2005)
The UK HTA (1) included one primary study that evaluated the use of PET in eight patients with gastric NHL. Due to its small population, the authors concluded that PET is unlikely to be used routinely for the diagnosis of lymphoma because histological confirmation is always required.

Studies published after August 2005
In adult patients, one study (3) evaluated the utility of FDG PET (no co-registered CT component) in primary central nervous system lymphoma diagnosis. Forty-two scans were performed for the purpose of initial diagnosis and staging. FDG PET scans were abnormal in eight of 42 patients. Biopsies were obtained in six of the patients, of which five revealed malignancy. In three patients, FDG PET revealed systematic NHL. Three patients had false-positive results.

Qualifying Statements:

- FDG PET may disclose higher rates of systemic disease; however, due to false-positive results, FDG PET scans should be subject to clinical follow-up or biopsy.

Staging

Recommendation(s):
When functional imaging is considered to be important in situations where anatomical imaging is equivocal, and/or in potentially curable cases, a FDG PET/CT scan is recommended.

When functional imaging is considered to be important in situations where anatomical imaging is equivocal and treatment choices may be affected in limited stage indolent lymphomas, a FDG PET/CT scan is recommended.

***Key Evidence*:**
UK HTA (studies prior to August 2005)
The UK HTA (1) evaluated several studies relating to the initial staging of HL and NHL. PET was consistently shown to be of superior sensitivity to Gallium (^{67}Ga) scanning, and was more accurate than or comparable with CT for staging.

Studies published after August 2005
In terms of patient management, the addition of FDG PET/CT modified the management of 8% to 32% of patients across included studies, with the majority of patients being upstaged as a result of the identification of distant disease.

Studies evaluating the utility of FDG PET or PET/CT for initial staging in patients with both HL and NHL showed similar results (4-14). In most studies, the specificity was high for both conventional imaging and FDG PET (often >90%); however, the sensitivities varied widely across studies and were generally low due to a prevalence of false-negative cases. In patients with mucosa-associated lymphoid tissue lymphoma, PET scans at baseline were reported to pick up more sites of disease than conventional staging tests (15-18).

In the detection of bone marrow involvement, FDG PET/CT correctly identified bone marrow involvement in approximately 95% of cases and patients were staged appropriately (5,19). FDG PET/CT was also shown to be useful in the planning of directed bone marrow biopsy.

Qualifying Statements:

- There was some evidence to suggest that FDG PET/CT may miss small disease foci; however, in studies that compared FDG PET/CT with ^{67}Ga scanning, the diagnostic accuracy of FDG PET/CT was shown to be superior.

- In most cases, FDG PET/CT changed the management of several patients. Most patients were upstaged due to the identification of advanced disease stage; however, due to poor reporting and short follow-up, the clinical relevance and whether the change resulted in a better clinical outcome of the upstaging was unclear.

Response Evaluation (interim and at completion of therapy)

Recommendation(s):
An FDG PET/CT scan is recommended for the assessment of early response in early stage (I or II) HL following two or three cycles of chemotherapy when chemotherapy is being considered as the definitive single-modality therapy, to inform completion of therapy or if more therapy is warranted.

***Key Evidence*:**
UK HTA (studies prior to August 2005)
The UK HTA (1) included nine primary studies and concluded that there was some weak evidence, consisting mainly of small-scale observational studies, suggesting that FDG PET/CT may be predictive of therapeutic response following two to three cycles of chemotherapy. There was no evidence to suggest that the addition of interim FDG PET/CT changed patient management (such as intensification or change in therapy).

Studies published after August 2005
Evidence suggests that FDG PET/CT scans are superior to conventional anatomical imaging in assessing response to treatment both interim and at completion (10,11,20-31). Interim PET scan results appear to carry powerful prognostic information that can be predictive for treatment failure in patients with NHL and HL undergoing primary therapy. The available evidence indicates that a PET-positive scan at the completion of therapy is associated with poorer prognosis. Also, in patients with relapsed lymphoma who are undergoing salvage chemotherapy and autologous stem cell transplantation, PET scan results appear to be an independent predictive factor for progression-free survival, but are not as strong for overall survival.

Qualifying Statements:

- For interim response to treatment, data around the role of PET in this population are continuing to evolve and patients should be involved in prospective clinical trials conducted in a multidisciplinary setting.

Diagnosis of Suspected Recurrence and Routine Follow-up

Recommendation(s):
In potentially curable cases, when functional imaging is considered to be important and conventional imaging is equivocal, a FDG PET/CT scan is recommended to investigate recurrence of HL or NHL.

An FDG PET/CT scan is recommended for the evaluation of residual mass(es) following chemotherapy in a patient with HL or NHL when further, potentially curative, therapy (such as radiation or stem cell transplantation) is being considered and when biopsy cannot be safely or readily performed.

***Key Evidence*:**
UK HTA (studies prior to August 2005)
The UK HTA (1) included five primary studies that demonstrated that FDG PET/CT was a better predictor of relapse after therapy than CT. When compared with ^{67}Ga scanning and CT scanning, post-therapy FDG PET/CT had a similar sensitivity and better specificity.

Studies published after August 2005
In regard to recurrence, the current recommendation report included six studies evaluating adult patients (11,20,32-35) and three studies evaluating pediatric patients (21,36,37). FDG PET/CT showed a good concordance with conventional imaging in the detection of recurrence; however, due to a prevalence of false-positive results in these studies, PET-positive patients may benefit from clinical follow-up.

In this recommendation report, 11 primary studies (3,7,9,11,14,38-43) investigating FDG PET/CT in the routine follow-up of patients with lymphoma showed similar results with no significant differences between HL and NHL or adult and pediatric patients. Both specificity and sensitivities were high and were in good concordance with conventional imaging. Several studies also provided evidence that a pretransplant FDG PET/CT scan contained predictive information on the long-term clinical outcome of patients (7,44-46).

Qualifying Statements:

- In cases where FDG PET/CT scans have a positive result, patients may benefit from close clinical follow-up or confirmatory biopsy due to a prevalence of false positives in the literature.

Routine Surveillance

Recommendation(s):
An FDG PET/CT scan is not recommended for the routine monitoring and surveillance of lymphoma.

***Key Evidence*:**
Studies published after August 2005
Three studies evaluated the efficacy of FDG PET/CT in the routine surveillance of lymphoma patients (20,32,33). All studies noted increased false positives as well as a lack of evidence of cost effectiveness compared with conventional imaging. The costs incurred as a result of the false positive results were unacceptably high.

Qualifying Statements:

- The current standard of practice in Ontario is to follow patients clinically with history, physical examination, and routine blood work.

Qualifying Statements Applicable to all Recommendations:

- In cases where FDG PET/CT scans have a positive result, patients may benefit from close clinical follow-up or confirmatory biopsy due to a prevalence of false positives in the literature.

- Although most individual studies outlined the technical aspects of how the FDG PET or PET/CT scan was performed and reported, in most studies, the scans were not read by blinded readers and it is unclear whether technical differences may make studies more difficult to compare with one another.

- PET scans are not assumed to be perfect tests and they are associated with variable rates of false-positive and false-negative rates. Practitioners should keep this in mind when interpreting the results of a PET scan.

- With respect to HIV-positive lymphoma patients, only small studies that did not meet the inclusion criteria were found in the systematic literature search; however, the authors are aware of a higher prevalence of false-positive FDG PET/CT results due to higher standardized uptake values in areas of inflammation.

FUTURE RESEARCH

Future research should focus on conducting randomized controlled trials with larger sample sizes focusing on clinically and histologically more homogeneous populations using standardized FDG PET/CT protocols and interpretation criteria. Better standardization of diagnostic criteria with the involvement of well-trained assessors should also be emphasized due to the potential of inter-reader variability. It should also be a priority to incorporate FDG PET/CT scan results in the design of randomized clinical trials to better direct patient management. It is suggested, where possible, that patients be enrolled in clinical trials of PET-directed therapy.

We searched www.clinicaltrials.gov for phase III studies in NHL or HL and PET. The following studies are ongoing:

- Positron Emission Tomography Guided Therapy of Aggressive Non-Hodgkin's Lymphomas
- Very Early FDG-PET/CT-response Adapted Therapy for Advanced Hodgkin Lymphoma (H11)
- ^{18}F-fluorodeoxyglucose (^{18}F-FDG) Positron Emission Tomography in Oncology
- Fluorodeoxyglucose F 18 PET Scan-Guided Therapy or Standard Therapy in Treating Patients With Previously Untreated Stage I or Stage II Hodgkin's Lymphoma
- PET Scan in Planning Treatment in Patients Undergoing Combination Chemotherapy For Stage IA or Stage IIA Hodgkin Lymphoma
- Study Evaluating the Non-inferiority of a Treatment Adapted to the Early Response Evaluated With ^{18}F-FDG PET Compared to a Standard Treatment, for Patients Aged From 18 to 80 Years With Low Risk (aa IPI = 0) Diffuse Large B-cells Non Hodgkin's Lymphoma CD 20+
- Study Evaluating the Non-inferiority of a Treatment Adapted to the Early Response Evaluated With ^{18}F-FDG PET Compared to a Standard Treatment, for Patients Aged From 18 to 80 Years With Low Risk (aa IPI = 0) Diffuse Large B-cells Non Hodgkin's Lymphoma CD 20+
- Fludeoxyglucose F 18-PET/CT Imaging in Assessing Response to Chemotherapy in Patients With Newly Diagnosed Stage II, Stage III, or Stage IV Hodgkin Lymphoma

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Contact Information

For further information about this report, please contact:

Sarah Kellett
Health Research Methodologist, Program in Evidence Based Care
Juravinski Hospital, G-Wing, Second Floor, Room 221
711 Concession Street, Hamilton, Ontario, L8V 1C3
Phone: 905-527-4322 ext. 42854 Fax: 905-526-6775 Email: kellett@mcmaster.ca

Dr. C. Tom Kouroukis
Associate Professor, McMaster University, Department of Oncology
Division Head, Malignant Hematology, Juravinski Cancer Centre, 3rd Floor
699 Concession Street, Hamilton Ontario, L8V 5C2
Phone: 905-387-9711 ext. 62487 Fax: 905-575-6340 E-mail: tom.kouroukis@jcc.hhsc.ca

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Phone: 905-527-4322 ext. 42822 Fax: 905 526-6775 E-mail: ccopgi@mcmaster.ca

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