FDG PET in Preoperative Assessment of Colorectal Liver Metastases Combining “Evidence-Based Practice” and “Technology Assessment” Methods to Develop Departmental Imaging Protocols: Should FDG PET Be Routinely Used in the Preoperative Assessment of Patients With Colorectal Liver Metastases?¹

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In today’s environment of progressively evolving and expensive imaging modalities, radiologists are asked to justify the use of resources to patients, referring physicians, hospital management, and third party payers. With this aim, the radiologist may use “top-down” or “bottom-up” “evidence-based practice” (EBP) techniques. “Top-down” suggests that the practitioner should wait until a higher authority, external to their practice, generates a solution to practice dilemmas (e.g., National Institute for Health and Clinical Excellence [NICE] guidelines). “Bottom-up” however, is based on the theory that the ordinary practitioner is best served by a decentralized approach to problem solving that is internal to their practice.

The technology assessment framework modeled by Mackenzie and Dixon comprehensively assesses the effects of imaging using levels of efficacy including diagnostic performance, diagnostic impact, and therapeutic impact, impact on health and cost effectiveness. In this article, we describe how issues regarding new imaging modalities in ordinary radiology practice can be addressed by using stepwise “bottom-up” EBP techniques combined with the technology assessment framework. We also detail how EBP techniques form an integral part of practice-based learning among radiology residents as part of noninterpretive residency training. The following clinical scenario is used: Your hospital’s chief hepatobiliary surgeon writes to your department regarding the lack of access to 18-fluoro-2-deoxy-D-glucose positron emission tomography in the preoperative assessment of patients with colorectal cancer liver metastases under consideration for hepatic resection. How would you approach this problem? Here is how we would do it.

Key Words. Colorectal neoplasm; liver; positron-emission tomography; evidence-based medicine; technology assessment; biomedical.

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CLINICAL SCENARIO

You are an attending radiologist in a busy hepatobiliary tertiary referral centre. The hepatobiliary surgical chairman writes a letter to you concerning the lack of availability of 18-fluoro-2-deoxy-D-glucose positron emission tomography (FDG PET) in the preoperative assessment of patients with colorectal cancer liver metastases (CRCLMs) who are under consideration for hepatic resection. The letter reads as follows:

As you know, the liver is the most frequent site for colorectal cancer metastasis with half of all patients with colorectal cancer developing liver metastases (1). More than 20% of patients with colorectal cancer have liver metastases at the time of diagnosis, while 40–60% of relapsed patients have CRCLMs (2). Hepatic resection of CRCLMs is the accepted standard of care and one of the few curative options available to patients.

Accurate preoperative staging is essential in the management of CRCLMs to prevent unnecessary laparotomy in patients who are found to be unresectable at surgery and correctly select those patients with potential for curative resection. FDG PET is a rapidly emerging clinical application in the detection of hepatic and extrahepatic colorectal metastases. Despite this, FDG PET is not available to all our patients being assessed for hepatic resection. It would appear the limited availability and the high cost of FDG PET are restricting its use. I note also in my own research regarding the imaging modality that there is very limited cost-effectiveness data on FDG PET.

I have found on a number of occasions that computed tomography (CT) and magnetic resonance imaging (MRI) have understaged patients on whom I have attempted hepatic resection. This has led to unnecessary surgery, morbidity, and cost. In the environment in which we work where there are limited resources with respect to intensive care unit beds and operating theater time, this is putting a strain on an overburdened service. I believe that FDG PET will stage this patient subgroup more accurately, will impact their management, and may prove to be cost effective.

Recently you used EBP techniques to justify the use of transarterial chemoembolization in the management of hepatocellular carcinoma (3) (Fig. 1). I would appreciate if you could again use EBP techniques to evaluate the role of FDG PET in the management of patients with CRCLMs.

You discuss this letter with several senior colleagues who agree that in order to establish the role of FDG PET in the preoperative evaluation of patients with CRCLMs, a stepwise process using EBP techniques should be used to identify the best current evidence with respect to its diagnostic performance, diagnostic impact, and therapeutic impact. Your colleagues agree that this might be a good opportunity to establish “practice-based learning” activities and incorporate them into the noninterpretive aspects of the residents’ training program within your department. It was thought that this could assist attending staff make decisions about “cutting-edge” issues and gray areas of practice. A small work group of residents in their second year of residency agree to take on the project and present their findings to the hepatobiliary service and hospital management next month. They prepare the following presentation:

The five-step process of evidence-based radiology

Step 1 ASK a focused clinical question
Step 2 SEARCH for the best current evidence
Step 3 APPRAISE validity & strength of evidence
Step 4 APPLY to patients / practice
Step 5 EVALUATE performance

Figure 1. The five-step process of evidence-based practice (3).

Those unfamiliar with the process (Fig. 1) can find a full description in the paper entitled “The Process of Evidence-Based Practice in Radiology: An Introduction” in this issue.

Step 1: Ask

The group posed a focused clinical question regarding the clinical scenario. The EBP question format PICO was used (Patient, Investigation, Comparison, and Outcomes of interest) (4). The question was written in text form as follows: “In patients with colorectal cancer, how does FDG PET compare to ultrasonography (US), CT, and MRI in the detection and characterization of liver metastases?”
Step 2: Search
MEDLINE, the National Library of Medicine (NLM) database, was accessed using the Advanced PubMed search engine. Articles were retrieved using the following words and medical subject headings (MeSH) terms that applied to the clinical question: colorectal metastasis, colorectal neoplasm, hepatic neoplasm, tomography, emission computed, ultrasonography, computerized tomography, magnetic resonance imaging, detection, and characterization.

Step 3: Appraise
The abstracts of publications retrieved with these searches were reviewed on PubMed and graded according to the levels of evidence described by the Centre for Evidence-Based Medicine (CEBM) (5). Thirty-eight relevant papers were appraised. There were two papers of level 2 evidence; the remaining articles were levels 3, 4, and 5. The level 2 article by Kinkel et al. (6) was appraised critically in detail. It is a meta-analysis of 39 case series comparing current noninvasive imaging methods such as US, CT, MRI, and FDG PET in the detection of hepatic metastases from colorectal, gastric, and esophageal cancers. The inclusion criteria identified data sets of patients for whom data were presented on a per-patient basis with a standard of reference of histopathological findings of at least one site of hepatic metastasis or 6-month to 1-year follow-up. Other data were included that looked at the sensitivity of FDG PET on a per-lesion basis. The reference standard for this group was histopathological diagnosis with or without the use of intraoperative US for all hepatic metastases. Kinkel et al. (6) performed a MEDLINE search that retrieved 1,260 abstracts. When inclusion and exclusion criteria were applied, 54 data sets remained. A specificity of at least 85% was considered clinically useful, leading to a subgroup of 39 data sets. The mean-weighted sensitivities of the various imaging modalities in studies with a specificity higher than 85% were as follows: 55% (95% confidence interval [CI], 41–68) for US, 72% (95% CI, 63–80) for CT, 76% (95% CI, 57–91) for MRI, and 90% (95% CI, 80–97) for FDG PET. The paper concluded, on the basis of the result of their meta-analysis, that FDG PET represents the most sensitive noninvasive modality for the detection of CRCLM. It suggested that the modality might have particular use in patients with increasing carcinoembyronic antigen levels and normal imaging findings.

A meta-analysis by Bipat et al. (7) that compared sensitivities of CT, MR, and FDG PET for detection of colorectal liver metastases on a per-patient and per-lesion basis was also analyzed. This paper looked solely at patients with CRCLM. The sensitivities reported on a per-patient basis for nonhelical CT, helical CT, 1.5-T MRI, and FDG PET were 60.2%, 64.7%, 75.8%, and 94.6%, respectively. However, on a per-lesion basis, the sensitivities were less impressive. Nonhelical CT, helical CT, 1.5-T MRI, and FDG PET had per-lesion sensitivities of 52.3%, 63.8%, 64.4%, and 75.9%, respectively. While this paper also showed that FDG PET was the most sensitive modality, it highlighted the lower sensitivity of all modalities on a per-lesion basis. It suggested that these sensitivities are more reflective of true diagnostic accuracy.

Four other papers were identified that were of interest as they specifically assessed FDG PET and its impact on the diagnosis and therapy of patients with suspected recurrence of colorectal cancer. These were predominantly level 3 and level 4 evidence studies. The results are summarized in Table 1. The prevailing opinion from these papers was that FDG PET had a significant impact on the diagnosis and management of patients with suspected recurrence of colorectal cancer.

Having completed Steps 1–3 of the EBP process (Ask, Search, Appraise), the findings are presented to the hepatobiliary surgical department and hospital management. They agree that in order to follow best practice, FDG PET should be incorporated into the work-up protocol for patients being assessed for resection of CRCLM. The hospital management will provide 18 months’ funding for FDG PET and have asked that local evidence be generated to evaluate the change in clinical practice before an ongoing commitment is given. You discuss this among your radiological colleagues afterward and decide to apply this evidence to your practice (Step 4).

Table 1

<table>
<thead>
<tr>
<th>Study*</th>
<th>Sample Size</th>
<th>Diagnostic Impact</th>
<th>Major Management Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simo et al [19]</td>
<td>120</td>
<td>—</td>
<td>48%</td>
</tr>
<tr>
<td>Kalff et al [24]</td>
<td>102</td>
<td>—</td>
<td>59%</td>
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<tr>
<td>Meta et al [25]</td>
<td>60</td>
<td>42%</td>
<td>37%</td>
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<tr>
<td>Imdahl et al [26]</td>
<td>71</td>
<td>—</td>
<td>20%</td>
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*Numbers in parentheses are reference numbers.
Step 4: Apply

Prior to the workgroup’s assessment of FDG PET, routine preoperative assessment included CT of the abdomen with a portal venous phase if available. The nature of indeterminate liver lesions was clarified using US or MRI with biopsy if needed. As a result of Steps 1–3, departmen
tal practice was changed and FDG PET was incorporated into the routine preoperative assessment of patients with CRCLM. All patients underwent helical CT of the thorax, abdomen, and pelvis with intravenous contrast. If patients were considered to be suitable candidates for hepatic resection, FDG PET was performed within 3 months. CT images acquired in other institutions were reviewed at the departmental hepatobiliary conference prior to a decision on FDG PET imaging. In 75% of pa
tients, imaging was performed on a single device (Somatom plus 4; Siemens Corporation, Forchheim, Germany). CT was performed with a slice thickness of 8 mm. Portal venous phase imaging was performed after intravenous administration of 100 ml of iodinated contrast agent. Patients were scanned using a full-ring, high-resolution, ded
cicated whole body PET scanner (General Electric Systems, Milwaukee, WI) with reconstructed image resolution of between 4 mm and 6 mm. Patients fasted from food for a minimum of 4 hours but drank two to six glasses of glucose-free fluid within 1 hour of arrival. Finger-prick capillary blood glucose testing was performed prior to scanning. A maximum cutoff of 8.0 mmol/L was applied, above which FDG administration and scanning were deferred. The patients were injected with 300 MBq to 400 MBq of FDG intravenously followed by 20 mg of IV frusemide. Patients remained lying in a dimly lit, quiet room for 45–60 minutes. The patients emptied their blad
der before transfer to the PET scanner. Both emission and transmission whole body scans were acquired, taking 40–60 minutes depending on the patient’s height. Transaxial images were processed using iterative reconstruction and segmental attenuation correction. Images were displayed in transaxial, coronal, and sagittal planes. Maximum intensity projection images for cine display were also produced.

Two radiologists with dual certification in radiology and nuclear medicine and fellowship experience in FDG PET and a consultant physician in nuclear medicine interpreted the FDG PET images. All images were viewed on a high-resolution workstation, and the FDG PET scans were correlated with the most recent CT scan (visual fusion).

Step 5: Evaluate the change in practice

In order to evaluate the change in practice, a retrospective review of patient records was performed. The following inclusion criteria were used: patients who were (i) undergoing FDG PET; (ii) had a diagnosis of colorectal carcinoma; (iii) had CRCLM on CT; and (iv) undergoing assessment for hepatic resection.

Having applied the findings of your literature review to the department’s practice, you then complete the EBP paradigm by evaluating the change in clinical practice by undertaking a clinical audit.

TECHNOLOGY ASSESSMENT

FDG PET was evaluated using the technology assessment levels of diagnostic and therapeutic impact as set out by an evaluative framework first suggested by Fineberg et al. (8) in a study of CT published in 1977. This scheme subsequently evolved into a six-level (9) (Fig. 2) and then a five-level evaluative framework (Fig. 3) modeled by Mackenzie and Dixon (10) with the recognition that the “diagnostic information” level addressed two separate questions: the diagnostic performance of imaging and its impact on diagnostic thinking in terms of confidence and utilization of other investigations. The resulting five-level hierarchy is becoming is widely acknowledged in the United Kingdom and Europe as appropriate for the assessment of diagnostic imaging and was found to be
practically more useful in this study. The framework provides a comprehensive and readily interpretable assessment of the effects of imaging.

The technical and diagnostic performance of FDG PET has been established in the literature (7, 10, 11). The diagnostic and therapeutic impact has been established, albeit to a lesser extent. The EBP group decided, after some discussion and the advice of the tutor (a staff radiologist with EBP training), to evaluate the local diagnostic and therapeutic impact of FDG PET. Diagnostic impact is defined as the extent to which the application of an imaging modality displaces an alternative diagnostic technique (i.e., FDG PET versus CT). The diagnostic impact of FDG PET was determined by assessing in a patient-based analysis the concordant and discordant findings between CT and FDG PET. Therapeutic impact measures the change in management as a result of the imaging modality. In this clinical scenario, a change in management included (i) upstaging, leading to cancellation of surgery, (ii) upstaging, leading to more extensive surgery, and (iii) downstaging, leading to the patient becoming eligible for resection. Ideally, a favourable diagnostic impact should lead to a favorable therapeutic impact in terms of initiation, change or withdrawal of planned therapy (10).

These parameters were determined by reviewing patient records to establish surgical intentions before and after FDG PET. Patient record review was performed by two investigators from the radiology resident workgroup, and results were decided by consensus. A comparison between the surgical and histopathological findings and lesions seen on FDG PET was performed when possible. Statistical methods used include Pearson’s correlation co-efficient and two-tailed P-values. Calculations were performed using the Statistical Package for Social Science Version 11.0 (SPSS Inc, Chicago, IL).

Thirty-three patients (21 males and 12 females) met the inclusion criteria. The abnormal findings included hepatic metastases in 100% (n = 33) and extrhepatic abnormalities in 17 of 33 patients (51.5%). Seventeen of 33 of patients (51.5%) underwent hepatic resection. Two of 33 patients (6%) had laparotomy only.

**DIAGNOSTIC IMPACT**

Discordances between CT and FDG PET were analyzed to measure the diagnostic impact of FDG PET. Twenty-five of 33 cases (75.7%) had a FDG PET result that was discordant with CT. Discordances in relation to hepatic metastases were present in 8 of 33 (24.2%). These related to the number of deposits visualized and lobes involved. FDG PET and CT were discordant with regard to extrhepatic abnormalities in 17 of 33 patients (51.5%). These findings occurred where lesions were detected with FDG PET but not seen with CT. Furthermore, FDG PET detected extrhepatic metastases in sites not scanned by CT, leading to targeted imaging and biopsy of these sites. Seventeen of 25 patients with discordant findings (68%) were upstaged based on FDG PET findings.

Five of 33 patients (15.1%) with extrhepatic hepatic abnormalities on FDG PET scan underwent hepatic resection. Two of these patients had biopsies of the thyroid gland and axilla, respectively, due to increased isotope uptake (Fig. 4). Both were benign and therefore confirmed false positives. A further two patients had increased isotope uptake in the spinous process of L2 and mediastinum, respectively. No deposits were identified in either location when correlated with CT/MRI. These patients were therefore not upstaged and proceeded to hepatic resection. No false negatives were identified. The final patient had a resectable presacral recurrence and proceeded to hepatic resection.

**THERAPEUTIC IMPACT**

In 17 of 33 patients (51.5%), FDG PET changed management. This comprised four categories:

1. Patients who were upstaged and had planned surgery cancelled: 11 of 17 (64.7%) of these pa-
tients were upstaged and deemed unresectable either because of the increased hepatic metastatic load (Fig. 5) or due to unresectable extrahepatic metastasis.

2. **Patients who were upstaged and had more extensive hepatic disease:** 2 of 17 (11.7%) patients had significant extension of hepatic resection margin as a result of additional disease noted in another hepatic lobe on FDG PET. One of these patients had a CT that revealed a 4-cm lesion in segment 4 of the liver. FDG PET showed a further 1.5-cm lesion in the right lobe of the liver. The second patient had CRCLM identified on CT involving segment 8 and segment 4b. FDG PET showed a further lesion anterior to the inferior vena cava that was found to be CRCLM intraoperatively. The patient underwent an extended right hemihepatectomy.

3. **Patients who were downstaged:** 3 of 17 patients (17.6%) fit into this category either because extrahepatic disease suggested on CT was excluded or highlighted as potentially resectable. The latter group were previously thought to be ineligible for surgery but FDG PET showed that extrahepatic disease (e.g., local colorectal recurrence) was resectable, and the patients were therefore considered for hepatic resection.

4. One patient had four cystic lesions in the liver on CT, but the presence of an enlarged lymph node at
the porta hepatis gave rise to the suspicion of the lesions being CRCLM. An FDG PET showed the cysts to be benign.

Of those patients for whom management was changed (n = 17), 11 patients underwent tumor upstaging and it was decided that surgery was inappropriate. Two patients previously suspected to have unresectable tumors were referred for resection as a result of FDG PET.

Eighteen patients proceeded to laparotomy for hepatic resection. FDG PET correlated with surgical findings in 16 of 18 patients (88.8%). This comparison between surgical and FDG PET findings was found to be statistically significant (P < .0001; r = 0.88). In the remaining two patients, one had a large metastasis adherent to the diaphragm and the second had deposits that proved too large to resect.

Having completed the five steps of the EBP approach, you present your findings at grand surgical rounds. Your radiology colleagues and the hepatobiliary surgeon are pleased that the agreed change of practice has improved the management of patients with CRCLM. It is decided to continue with the updated protocol using FDG PET in the routine assessment of patients with CRCLM.

**DISCUSSION**

**The Five-Step EBP Process Can Be Used to Devise Department Protocols**

A clinical scenario was used to demonstrate how the five-step EBP process can be used to develop departmental protocols. EBP equips physicians with the tools to find, competently appraise, and interpret the medical literature. These techniques can be used by radiologists in a standard hospital setting as this narrative review has shown. The underlying assumption is that the ordinary practitioner is best served by a decentralized but exact approach, internal to his or her practice: “bottom-up.” Resident EBP groups have a potential role in practice-based learning and improvement. Practice-based learning is one of the six general competencies endorsed by the Accreditation Council for Graduate Medical Education (ACGME) in their accreditation of residency education programs (12). EBP techniques enable the resident to critically assess literature, to develop his or her knowledge of EBM, and to participate in departmental quality improvement activities.

**The Technology Assessment Framework Is Useful in Assessing FDG PET**

In this narrative review, the technology assessment framework was useful in assessing FDG PET and was used synergistically with the five steps of EBP. The technology assessment framework was originally proposed in 1991 by Fryback and Thornbury (13) and then modified by Mackenzie and Dixon (10). A more detailed description of the framework is available in the paper entitled “The Process of Evidence-Based Practice in Radiology: An Introduction” in this issue.

A sixth level has been described by Thornbury and Fryback that assesses the societal benefit of an imaging modality including cost-benefit analysis and cost-effectiveness studies. Cost-effectiveness data are limited in relation to FDG PET and CRCLMs, but a recent economic impact study of patients with CRCLM being assessed for hepatic resection showed a substantial reduction in overall cost and patient morbidity with a net saving of $5,269 per patient when FDG PET was used. These savings were due to the ability of FDG PET to identify patients with extrahepatic disease and avoid unnecessary surgery (14).

**FDG PET Has a Diagnostic Impact**

Hepatic resection provides long-term survival and cure for approximately one third of resected patients (15). Patients undergoing curative resection have a median survival of 37 months, while without hepatic resection; patients with metastases have a median survival of 6 (16) to 16 months (17). When patients proceed to hepatic resection on the basis of CT alone, up to 42% of patients are found to be unresectable intraoperatively (17). Laparotomy without preoperative FDG PET permits discovery of unsuspected intrahepatic and extrahepatic metastases in one third of patients with resectable CRCLM on CT (18).

All accept this is a small study but our findings indicate that FDG PET does have a diagnostic and therapeutic impact. In Step 5 (Evaluate), 75% of patients had discordances between CT and FDG PET. Hepatic discordances were related to the number of lesions detected and the lobes involved. Studies have shown that CT frequently misses deposits within the liver and underestimates lobar involvement in up to 33% of patients (19). A prospective trial found that the two modalities have a similar sensitivities for the detection of hepatic metastases (79%) but FDG PET displayed a far greater specificity than CT in ruling out CRCLM (80% versus 25%, respectively) (20). Another prospective clinical trial of 28 pa-
patients with CRCLMs found that FDG PET detected all CRCLMs (sensitivity of 100%) while CT incorrectly diagnosed solitary CRCLMs in five patients and failed to detect extrahepatic metastases in four patients (sensitivity of 47%) (1).

The majority of these discordances in Step 5 (Evaluate) involved extrahepatic metastases (68%). In relation to the advantage of FDG PET in detecting extrahepatic metastases, the findings are similar to the results of a recent prospective trial that found FDG PET to be superior to CT for detection of extrahepatic disease (20). In that trial, FDG PET had a sensitivity of 63% compared with that of CT (25%). In this article, the evaluation of FDG PET also identified the dilemma of potential extrahepatic false positives in 4 of 33 patients (12%). This was overcome by direct biopsy and further correlation with CT. This problem was also encountered in a similar study of 53 patients that described the discovery of extrahepatic false positives in 3 patients and one false positive hepatic lesion. This was overcome by biopsy and 12-month follow-up with CT (20).

FDG PET Has a Therapeutic Impact

FDG PET enables accurate detection of CRCLM prior to surgery. It is significantly better than CT in this regard and thus correctly selects those eligible for hepatic resection and excludes those who are not. This allows accurate planning of hepatic resection and avoids inappropriate laparotomy. In this small study, it was found that 17 of 33 (51.5%) of patients had a change of management as a result of FDG PET and 11 of these patients (76.5%) were upstaged. The most significant impact therefore was in the cancellation of planned surgery which occurred in 33.3% of patients. This is a more significant number than the findings of a retrospective trial that found that 4 of 16 patients studied had a management change due to FDG PET (21). That trial however looked solely at the diagnosis of liver abnormalities; the investigators concluded that FDG PET had a particular impact on patients with equivocal findings on CT or elevated carcinoembryonic antigen (CEA) without CRCLM on CT. A smaller trial demonstrated a management change in 42% of patients as a result of FDG PET (1). This study analyzed patients with both CRCLMs and extrahepatic metastases. A larger clinical trial recruited 120 patients with suspected colorectal metastasis (19). It found that FDG PET brought about a large management change in 48% of patients.

Recent data regarding patient outcome as a result of FDG PET has also been favorable. In a prospective trial, FDG PET was associated with a 5-year survival in patients with CRCLM after hepatic resection of 58% (22); this was a significant improvement when compared to a previous study of patients who did not have FDG PET preoperatively that demonstrated a median 5-year survival of 30% after hepatic resection (17).

FDG PET Is Effective

Efficacy and effectiveness are important measures of an imaging modality. Efficacy is defined as “the probability of benefit to individuals in a defined population from a medical technology applied for a given problem under ideal conditions” (23). Effectiveness, in contrast, is defined as “performance of a medical technology under ordinary, rather than ideal, conditions” (23). Our five-step review, therefore, assessed the effectiveness rather than the efficacy of FDG PET. One of the limitations of the systematic review performed by Kinkel et al. was that the studies included in the review were performed by experts in nuclear medicine in an optimal clinical setting, that is, “top-down” settings. Nonetheless, the findings of this review approximate the results of such studies, and therefore the effectiveness of FDG PET was found to be similar to reports of its efficacy.

CONCLUSION

This series demonstrates the application of steps 1–5 of EBP and how it can be combined synergistically with the technology assessment paradigm to evaluate new imaging modalities. Recent best evidence suggests that FDG PET can have a major diagnostic and therapeutic impact at the local “effectiveness” level. The routine use of FDG PET in the preoperative assessment of patients with CRCLMs can be justified pending the publication of larger prospective trials.

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