Dual injection PET/CT-guided intervention for ablation of liver metastases in a patient with colon carcinoma

By Paul B. Shyn, MD
Data courtesy of Brigham & Women’s Hospital, Boston, MA, USA

History
A 67-year-old woman with metastatic colorectal carcinoma with previous history of left lateral hepatic segmentectomy for metastases presented with recurrence in the liver at the resection margin. In view of a solitary liver metastasis amenable to percutaneous ablation, the patient was admitted for image-guided microwave ablation.

Imaging and therapy
Microwave ablation was planned to include $^{18}$F FDG PET/CT metabolic imaging guidance with second injection of $^{18}$F FDG to assess perfusion of peritumoral liver tissue to confirm complete tumor ablation with an adequate margin. On the day of ablation therapy, the patient was injected with 8mCi (296 MBq) of Fludeoxyglucose F18 ($^{18}$F FDG) about 1 hour prior to ablation therapy. The patient was brought into the Advanced Multimodality Image Guided Operating (AMIGO) suite equipped with the Biograph™ mCT (configured with CT Fluoroscopy). The patient was placed under general anesthesia. An initial planning PET/CT was performed with the patient supine in the treatment position. Both CT and PET acquisitions were acquired covering a single bed position over the liver during suspended respiration under general anesthesia. The CT and PET images were both acquired during a single 30-second breath-hold and were obtained under suspended ventilation in order to eliminate respiratory motion and ensure optimal image registration.

The fused PET/CT images were used to plan the location of insertion of the microwave ablation probe, along with its direction and distance to the tumor. A single microwave probe was inserted following a small skin incision and advanced to the planned depth based on the PET/CT. After confirmation of the correct positioning of the microwave probe within the tumor by another PET/CT (similar to the initial one using another 30-second suspension of ventilation to eliminate respiratory motion), the microwave ablation was performed. Immediately after ablation, a contrast enhanced CT followed by PET acquisition using suspended ventilation for 30 seconds was performed to determine the extent of the ablation zone and assess the amount of residual hypermetabolic tumor beyond the ablation zone.
Fludeoxyglucose F 18 5-10mCi as an IV injection
Indications and Usage

Fludeoxyglucose F 18 Injection is indicated for positron emission tomography (PET) imaging in the following settings:
• Oncology: For assessment of abnormal glucose metabolism to assist in the evaluation of malignancy in patients with known or suspected abnormalities found by other testing modalities, or in patients with an existing diagnosis of cancer.
• Cardiology: For the identification of left ventricular myocardium with residual glucose metabolism and reversible loss of systolic function in patients with coronary artery disease and left ventricular dysfunction, when used together with myocardial perfusion imaging.
• Neurology: For the identification of regions of abnormal glucose metabolism associated with foci of epileptic seizures.

Important Safety Information

• Radiation Risks: Radiation-emitting products, including Fludeoxyglucose F 18 Injection, may increase the risk for cancer, especially in pediatric patients. Use the smallest dose necessary for imaging and ensure safe handling to protect the patient and health care worker.
• Blood Glucose Abnormalities: In the oncology and neurology setting, suboptimal imaging may occur in patients with inadequately regulated blood glucose levels. In these patients, consider medical therapy and laboratory testing to assure at least two days of normoglycemia prior to Fludeoxyglucose F 18 Injection administration.
• Adverse Reactions: Hypersensitivity reactions with pruritus, edema and rash have been reported; have emergency resuscitation equipment and personnel immediately available. Full prescribing information for Fludeoxyglucose F 18 Injection can be found at the conclusion of this publication.

Dosage Forms and Strengths

Multiple-dose 30 mL and 50 mL glass vial containing 0.74 to 7.40 GBq/mL (20 to 200 mCi/mL) of Fludeoxyglucose F 18 injection and 4.5 mg of sodium chloride with 0.1 to 0.5% w/w ethanol as a stabilizer (approximately 15 to 50 mL volume) for intravenous administration. Fludeoxyglucose F 18 injection is manufactured by Siemens’ PETNET Solutions, 810 Innovation Drive, Knoxville, TN 39732

As shown on Figure 3, the ablated tumor retains pre-procedurally administered ¹⁸F FDG on the post ablation PET/CT performed with administration of CT contrast. The tumor uptake of ¹⁸F FDG in relation to the hypoenhancing ablation zone seen on the fused images confirms that the ablation zone is inadequate at the supero-medial aspect of the tumor. Based on the delineation of the post ablation PET/CT, an overlapping microwave ablation was further performed in order to extend the ablation of the supero-medial margin and include the entire metastatic tumor.

Following the second microwave ablation procedure, a PET perfusion study was performed to demonstrate the perfusion of the unablated liver surrounding the ablation zone. A second dose of 3mCi (111 MBq) of ¹⁸F FDG was injected and five minutes later a single bed position PET/CT acquisition was performed during a 60-second breath-hold with suspended ventilation in order to eliminate respiratory motion.

The trapped ¹⁸F FDG within the tumor after ablation enabled persistent visualization of the entire tumor. The
Contrast enhanced CT depicts hypoenhancing ablation zone as a region of low attenuation (orange arrow). Tumor margins cannot be defined on contrast CT only and fused PET/CT images acquired with suspended ventilation show the $^{18}$F FDG uptake within the tumor fused with the hypoenhanced ablation zone which demonstrates substantial amount of $^{18}$F FDG avid tumor to be at the medial margin of the ablation zone (white arrow) thereby confirming inadequate ablation.

The second injection of $^{18}$F FDG demonstrated perfusion of the normal liver tissue following the completion of the microwave ablation with increased contrast between well-perfused normal liver tissue and non-perfused ablation zone thereby clearly demonstrating the ablation zone margins and confirming that the entire metastatic tumor has been covered by the ablation zone. The tumor shows $^{18}$F FDG from the pre-procedural injection trapped within it and PET/CT images acquired without respiratory motion is clearly able to define the margin of the tumor and that of the hypoperfused ablation zone and confirm that the ablation zone completely covers the entire tumor thereby confirming a successful ablation procedure without evidence of residual tumor.

**Comments**

Microwave ablation achieves tumor cell killing by heating of tissues ultimately leading to coagulation necrosis. Uptake of $^{18}$F FDG within the tumor does not dissipate following microwave ablation as evident from the persistent $^{18}$F FDG uptake within the tumor immediately after the microwave ablation, which helps determine the extent of coverage of the ablation zone following microwave ablation and presence of hypermetabolic tumor beyond the ablation zone. As demonstrated by the PET/CT images acquired immediately after the initial microwave ablation, a substantial amount of tumor laid beyond the margins of the initial ablation and a subsequent ablation was required to ensure complete tumor coverage. However, to better visualize the extent of microwave ablation, a second $^{18}$F FDG injection and a subsequent breath-hold PET/CT acquisition immediately following the injection was required to demonstrate the perfusion of the normal liver tissue around the microwave ablation zone which does not have any perfusion. The increased perfusion of the normal liver and the complete absence of perfusion in the ablation zone creates a sharp contrast in $^{18}$F FDG uptake which helps visually ascertain the exact margin of the ablation zone and clearly determine if the tumor (which shows $^{18}$F FDG uptake trapped within it from the pre-procedural injection) has been adequately covered by the ablation zone or not. In this case, the second ablation procedure guided by PET/CT was adequate to cover the entire tumor.
Conclusion

$^{18}$F FDG PET/CT acquired with breath-hold created by suspension of ventilation during anesthesia can help guide microwave ablation procedures and help achieve complete ablation of tumor. In this case example, a second injection of $^{18}$F FDG improves visualization of ablation margins by demonstrating perfusion of normal liver and highlighting the contrast between normally perfused liver and non-perfused ablation zone margins. The use of a widely available isotope, such as $^{18}$F FDG*, to demonstrate liver perfusion in this way can further expand the use of PET/CT guided ablation procedures.

PET/CT image acquired 5 minutes after second injection of $^{18}$F FDG following microwave ablation shows complete coverage of the tracer avid tumor by the ablation zone which appears as a region of hypodensity on CT with a photopenic margin (see arrow). $^{18}$F FDG uptake within the tumor appears unchanged and reflects uptake from pre-procedural injection which is trapped within the ablation zone. Activity in the normally perfused liver, especially in the normal liver tissue around the margin of the hypometabolic ablation zone (see arrow) is increased due to the second injection of $^{18}$F FDG. Due to the increased perfusion of the normal liver, the hypometabolic and non-perfused ablation zone is clearly visible with photopenic ablation margins which confirm complete coverage of the hypermetabolic metastatic tumor.

Examination Protocol

Scanner: Biograph mCT

<table>
<thead>
<tr>
<th>PET/CT</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Injected Dose</td>
<td>8mCi; 3mCi (second injection) $^{18}$F FDG</td>
</tr>
<tr>
<td>Scan Delay</td>
<td>60 min</td>
</tr>
<tr>
<td>Acquisition</td>
<td>30 sec breath-hold single bed position</td>
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</table>

<table>
<thead>
<tr>
<th>CT</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Tube Voltage</td>
<td>130 kV</td>
</tr>
<tr>
<td>Tube current</td>
<td>60 mAs</td>
</tr>
<tr>
<td>Slice collimation</td>
<td>64x0.6 mm</td>
</tr>
<tr>
<td>Slice thickness</td>
<td>5 mm</td>
</tr>
</tbody>
</table>

*The full prescribing information can be found at the conclusion of this publication.
Fludeoxyglucose F 18 Injection, USP

INDICATIONS AND USAGE

Fludeoxyglucose F 18 Injection is indicated for:

- In the cardiology setting, administration of fludeoxyglucose F 18 Injection safely and effectively facilitates localization of cardiac ischemia (2.3).
- For assessment of abnormal glucose metabolism to assist in the evaluation of malignancy (2.7).
- For the identification of left ventricular myocardium with residual glucose metabolism and reversible loss of systolic function in patients with coronary artery disease and left ventricular dysfunction, when used together with myocardial perfusion imaging (2.3).

ADVERSE REACTIONS

- Radiation risks: use smallest dose necessary for imaging (5.1).
- Blood glucose abnormalities: may cause subclinical imaging (5.1).
- Hypersensitivity reactions have occurred; have emergency resuscitation equipment and personnel immediately available (6).

CONTRAINDICATIONS

None (4).

WARNINGS AND PRECAUTIONS

- The dynamic bladder model with a uniform voiding frequency of 1.5 hours was used. *LLI = lower large intestine; **ULI = upper large intestine.

2 DOSAGE AND ADMINISTRATION

- The recommended dose: for adults is 5 to 10 mCi (185 to 370 MBq) as an intravenous injection.
- Reagent sodium fluoride solution 0.74 to 4.90 GBq/mL (20 to 100 mCi/mL) Fludeoxyglucose F 18 Injection and 4.5mg of sodium chloride with 0.1 to 0.5% w/w ethanol as a stabilizer (approximately 15 to 50 mL/volume) for intravenous administration (3).

3 DOSAGE FORMS AND STRENGTHS

Multi-dose 30mL and 50mL glass vials containing 30 to 100 minutes from time of injection (2).

4 CONTRAINDICATIONS

For intravenous use only. Use procedures to minimize radiation exposure (6).

5 WARNINGS AND PRECAUTIONS

- Screen patients for clinically significant blood glucose abnormalities by obtaining a history and/or laboratory tests [see Warnings and Precautions (5.2)]. Prior to Fludeoxyglucose F 18 PET imaging in the oncology and neurology settings, instruct patient to fast for 4 to 6 hours prior to the drug's injection.
- In the cardiology setting, administration of glucose-containing food or liquids (e.g., 50 to 75 grams) prior to Fludeoxyglucose F 18 Injection facilitates localization of cardiac ischemia (2.3).

6 ADVERSE REACTIONS

- 1.3 Neurology
- 2.7 Imaging Guidelines
- 2.6 Drug Preparation and Administration
- 2.3 Patient Preparation
- 1.1 Oncology
- 1.2 Cardiology
- 1.3 Neurology
- 5.1 Radiation Risks
- 5.2 Blood Glucose Abnormalities
- 6 Adverse Reactions
- 7 Drug Interactions
- 8 Use in Specified Populations
- 8.1 Pregnancy

7 DRUG INTERACTIONS

8 USE IN SPECIFIED POPULATIONS

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22 HOW SUPPLIED/STORAGE AND HANDLING

23 PATIENT COUNSELING INFORMATION

24 RADIATION DOSIMETRY

25 Table 1. Estimated Absorbed Radiation Doses (rem/mCi) After Intravenous Administration of Fludeoxyglucose F 18 Injection*
2.5 Radiation Safety – Drug Handling
- Use waterproof gloves, effective radiation shielding, and appropriate safety measures when handling Fludeoxyglucose F 18 Injection to avoid unnecessary radiation exposure to the patient, occupational workers, clinical personnel and other persons.
- Radiopharmaceuticals should be used by or under the control of physicians who are qualified by specific training and experience in the safe use and handling of radionuclides, and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radionuclides.
- Calculate the final dose from the end of synthesis (EOS) time using proper radioactive decay factors. Assay the final dose in a properly calibrated dose calibrator before administration to the patient [see Description (1.2)].
- The dose of Fludeoxyglucose F 18 used in a given patient should be minimized consistent with the objectives of the procedure, and the nature of the radiation detection devices employed.

2.6 Drug Preparation and Administration
- Calculate the necessary volume to administer based on calibration time and dose.
- Aseptically withdraw Fludeoxyglucose F 18 Injection from its container.
- Inspect Fludeoxyglucose F 18 Injection visually for particulate matter and discoloration before administration, whenever solution and container permit.
- Do not administer the drug if it contains particulate matter or discoloration; dispose of these unacceptable or unused preparations in a safe manner, in compliance with applicable regulations.
- Use Fludeoxyglucose F 18 Injection within 12 hours from the EOS.

2.7 Imaging Guidelines
- Initiate imaging within 40 minutes following Fludeoxyglucose F 18 Injection administration.
- Acquire static emission images 30 to 100 minutes from the time of injection.

3 DOSE FORMS AND STRENGTHS
- Multiple-dose 30 mL and 50 mL glass vial containing 0.74 to 7.40 GBq/mL (20 to 200 mCi/mL) of Fludeoxyglucose F 18 Injection and 4.5 mg of sodium chloride with 0.1 to 0.5% w/v ethanol as a stabilizer (approximately 15 to 50 mL volume) for intravenous administration.

4 ADVERSE REACTIONS
- Hypersensitivity reactions with pruritus, edema and rash have been reported in the diagnostic purposes in conjunction with positron emission tomography (PET) imaging.
- Administration of Fludeoxyglucose F 18 to pregnant women or can affect reproduction capacity. Consider alternative diagnostic tests in a pregnant woman; administer Fludeoxyglucose F 18 Injection only if clearly needed.

6 ADVERSE REACTIONS
- Hypersensitivity reactions with pruritus, edema and rash have been reported in the post-marketing setting. Have emergency resuscitation equipment and personnel immediately available.

7 DRUG INTERACTIONS
- The possibility of interactions of Fludeoxyglucose F 18 Injection with other drugs taken by patients undergoing PET imaging has not been studied.

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
- Pregnancy Category C
- Animal studies have not been conducted with Fludeoxyglucose F 18 Injection. It is also not known whether Fludeoxyglucose F 18 Injection can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Consider alternative diagnostic tests in a pregnant woman; administer Fludeoxyglucose F 18 Injection only if clearly needed.

8.3 Nursing Mothers
- It is not known whether Fludeoxyglucose F 18 Injection is excreted in human milk. Consider alternative diagnostic tests in a breastfeeding woman; administer Fludeoxyglucose F 18 Injection only if clearly needed.

8.4 Pediatric Use
- The safety and effectiveness of Fludeoxyglucose F 18 Injection in pediatric patients with epilepsy is established on the basis of studies in adults and pediatric patients. In pediatric patients with epilepsy, the recommended dose is 2.6 mCi. The optimal dose adjustment on the basis of body size or weight has not been determined. In the oncology and neurology setting, suboptimal imaging may occur in patients with inadacutely regulated blood glucose levels. In these patients, consider medical therapy and laboratory testing to assure at least two days of normoglycemia prior to Fludeoxyglucose F 18 injection administration.

8.5 Warnings and Precautions
- Radiation Risks
  - Radiation-emitting products, including Fludeoxyglucose F 18 Injection, may increase the risk for cancer, especially in pediatric patients. Use the smallest dose necessary for imaging and ensure safe handling to protect the patient and health care worker [see Dose and Administration (2.5)].

5.2 Blood Glucose Abnormalities
- In the oncology and neurology setting, suboptimal imaging may occur in patients with inadacutely regulated blood glucose levels. In these patients, consider medical therapy and laboratory testing to assure at least two days of normoglycemia prior to Fludeoxyglucose F 18 injection administration.

10.4 Pharmacodynamics
- Fluorine F 18 decays by emitting positron to Oxygen O 16 (stable) and has a physical half-life of 109.7 minutes. The principal photons useful for imaging are the dual 511 keV gamma photons, that are produced simultaneously in opposite direction when the positron interacts with an electron (Table 2).

11.2 Physical Characteristics
- Fluorine F 18 decays by emitting positron to Oxygen O 16 (stable) and has a physical half-life of 109.7 minutes. The principal photons useful for imaging are the dual 511 keV gamma photons, that are produced simultaneously in opposite direction when the positron interacts with an electron (Table 2).

Table 2. Principal Radiation Emission Data for Fluorine F 18

<table>
<thead>
<tr>
<th>Emission/Decay</th>
<th>% Disintegration</th>
<th>Mean Energy</th>
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<tbody>
<tr>
<td>Positron (β+)</td>
<td>96.73</td>
<td>249.8 keV</td>
</tr>
<tr>
<td>Gamma (γ)</td>
<td>3.27</td>
<td>511.0 keV</td>
</tr>
</tbody>
</table>

*Produced by positron annihilation

From: Kocher, D.C. Radioactive Decay Table DOE/TIC-1 1026, 89 (1981). The specific gamma ray constant (point source air kerma coefficient) for fluorine F 18 is 5.78 x 10^-3 Gy/rad(Bq) at 1 cm. The half-value layer (HVL) for the 511 keV photons is 4 mm lead (Pb). The range of attenuation coefficients for this radionuclide as a function of lead shield thickness is shown in Table 3. For example, the interposition of an 8 mm thickness of Pb, with a coefficient of attenuation of 0.25, will decrease the external radiation by 75%.

Table 3. Radiation Attenuation of 511 keV Photons by Lead (Pb) shielding

<table>
<thead>
<tr>
<th>Shield thickness (Pb) mm</th>
<th>Coefficient of attenuation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>4</td>
<td>0.50</td>
</tr>
<tr>
<td>8</td>
<td>0.25</td>
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<td>13</td>
<td>0.10</td>
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<tr>
<td>26</td>
<td>0.01</td>
</tr>
<tr>
<td>39</td>
<td>0.001</td>
</tr>
<tr>
<td>52</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

*calibration time

12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
- Fluorine F 18 is a glucose analog that concentrates in cells that rely upon glucose as an energy source, or in cells whose dependence on glucose increases under pathophysiological conditions. Fludeoxyglucose F 18 is transported through the cell membrane by facilitative glucose transporter proteins and is phosphorylated within the cell to [18F] FDG-6-phosphate by the enzyme hexokinase. Once phosphorylated it cannot exit until it is dephosphorylated by glucose-6-phosphatase. Therefore, within a given tissue or pathophysiological process, the retention and clearance of Fludeoxyglucose F 18 reflect a balance involving glucose transporter, hexokinase and glucose-6-phosphatase activities. Since any change in these activities can alter the kinetic differences between glucose and Fludeoxyglucose F 18 transport and phosphorylation (expressed as the ‘lumped constant’ ratio). Fludeoxyglucose F 18 is used to assess glucose metabolism.

12.2 Pharmacodynamics
- Fludeoxyglucose F 18 Injection is rapidly distributed to all organs of the body after intravenous administration. After background clearance of Fludeoxyglucose F 18 Injection, optimal PET imaging is generally achieved between 30 to 40 minutes after administration.

12.3 Pharmacokinetics
- In cancer, the cells are generally characterized by enhanced glucose metabolism partially due to (1) an increase in activity of glucose transporters, (2) an increased rate of phosphatase activity, (3) a reduction of phosphatase activity or, (4) a dynamic alteration in the balance among all these processes. However, glucose metabolism of cancer as reflected by Fludeoxyglucose F 18 accumulation shows considerable variability. Depending on tumor type, stage, and location, Fludeoxyglucose F 18 accumulation may be increased, normal, or decreased. Also, inflammatory cells can have the same variability of uptake as normal cells.

In the heart, under normal aerobic conditions, the myocardium may meet the bulk of its energy requirements by oxidizing free fatty acids. Most of the exogenous glucose taken up by the myocardium is metabolized immediately instead of being converted into glycogen. However, under ischemic conditions, the oxidation of free fatty acids decreases, exogenous glucose becomes the preferred myocardial sub state. Glycolysis is stimulated, and glucose taken up by the myocyte is metabolized immediately instead of being converted into glycogen. Under these condi-
Fludeoxyglucose F 18 Injection, USP

tions, phosphorylated Fludeoxyglucose F 18 accumulates in the myocyte and can be detected with PET imaging.

In the brain, cells normally rely on aerobic metabolism. In epilepsy, the glucose metabolism is impaired. Generally, during a seizure, glucose metabolism increases. Intracereally, the seizure focus tends to be hypometabolic.

12.3 Pharmacokinetics

**Distribution:** In four healthy male volunteers, receiving an intravenous administration of 30 MBq (0.8 mCi) of Fludeoxyglucose F 18 radiolabeled carbon-11, the arterial blood level profile for Fludeoxyglucose F 18 decayed triexponentially. The effective half-life ranges of the three phases were 0.2 to 0.3 minutes, 10 to 13 minutes with a mean and standard deviation (STD) of 11.6 ± 1.1 min, and 80 to 95 minutes with a mean and STD of 88 ± 4 min.

**Metabolism:** Fludeoxyglucose F 18 is transported into cells and phosphorylated to [F-18] 2-deoxy-2-[F-18]fluoro-D-glucose (ClDG)). Biodistribution and metabolism of ClDG are presumed to be similar to FDG-phosphorylating enzymes in animals, thereby inhibiting glucose transport into cells. ClDG presumably leaves cells by passive diffusion. Fludeoxyglucose F 18 and related compounds are cleared from the urinary bladder at two hours post-administration suggests that 20.6% (mean) of the administered dose was measured in the urine. The amount of radiation exposure of the bladder at two hours post-administration suggests that 20.6% (mean) of the radioactive dose was present in the bladder.

**Special Populations:**

The pharmacokinetics of Fludeoxyglucose F 18 Injection have not been studied in renally-impaired, hepatically impaired or pediatric patients. Fludeoxyglucose F 18 is eliminated from the body by urine excretion. In four healthy male volunteers, receiving an intravenous administration of 30 MBq (0.8 mCi) of Fludeoxyglucose F 18 radiolabeled carbon-11, the arterial blood level profile for Fludeoxyglucose F 18 decayed triexponentially. The effective half-life ranges of the three phases were 0.2 to 0.3 minutes, 10 to 13 minutes with a mean and standard deviation (STD) of 11.6 ± 1.1 min, and 80 to 95 minutes with a mean and STD of 88 ± 4 min.

13 Carcinogenesis, Mutagenesis, Impairment of Fertility

Animal studies have not been performed to evaluate the Fludeoxyglucose F 18 Injection carcinogenic potential, mutagenic potential or effects on fertility.

14 CLINICAL STUDIES

14.1 Oncology

*The efficacy of Fludeoxyglucose F 18 Injection in position emission tomography cancer imaging was demonstrated in 16 independent studies. These studies prospectively evaluated the use of Fludeoxyglucose F 18 Injection in patients with suspected or known malignancies. The patients included non-small cell lung cancer, colorectal, pancreatic, breast, thyroid, melanoma, Hodgkin’s and non-Hodgkin’s lymphoma, and various types of metastatic cancers to lung, liver, bone, and axillary nodes. All these studies had at least 50 patients and used pathological and/or radiological images to evaluate the Fludeoxyglucose F 18 Injection doses in the studies ranged from 200 MBq to 740 MBq with a median and mean dose of 370 MBq. In the studies, the diagnostic performance of Fludeoxyglucose F 18 Injection varied with the type of cancer, size of cancer, and other clinical conditions. False negative and false positive scans were observed. Negative Fludeoxyglucose F 18 Injection PET scans do not exclude the diagnosis of cancer. Positive Fludeoxyglucose F 18 Injection PET scans can be used to establish a diagnosis of cancer. Non-malignant conditions such as fungal infections, inflammatory processes and benign tumors have patterns of increased glucose metabolism that may give rise to false-positive scans. The efficacy of Fludeoxyglucose F 18 Injection PET imaging in cancer screening was not studied.*

14.2 Cardiology

*The efficacy of Fludeoxyglucose F 18 Injection for cardiac use was demonstrated in ten independent, prospective studies of patients with coronary artery disease and chronic left ventricular systolic dysfunction who were scheduled to undergo coronary revascularization. Before revascularization, patients underwent PET imaging with Fludeoxyglucose F 18 Injection (74 to 370 MBq, 2 to 10 mCi) and perfusion imaging with other diagnostic radiopharmaceuticals. Doses of Fludeoxyglucose F 18 Injection ranged from 74 to 370 MBq (2 to 10 mCi). Ventricular, wall-motion, and stress-induced wall-motion assessments of asynergic areas made before revascularization were compared in a blinded manner to assessments made after successful revascularization to identify myocardial segments with functional recovery. Left ventricular myocardial segments were predicted to have reversible loss of systolic function if they showed Fludeoxyglucose F 18 accumulation and reduced perfusion (i.e., flow-metabolism mismatch). Conversely, myocardial segments were predicted to have irreversible loss of systolic function if they showed reductions in both Fludeoxyglucose F 18 accumulation and perfusion (i.e., matched defects). Findings of flow-metabolism mismatch in a myocardial segment may suggest that successful revascularization will restore myocardial function in that segment. However, false-positive tests occur regularly, and the decision to have a patient undergo revascularization should not be based on PET findings alone. Similarly, findings of a matched defect in a myocardial segment may suggest that myocardial function will not recover in that segment, even if it is successfully revascularized. However, false-negative tests occur regularly, and, as a decision to recommend against coronary revascularization, or to recommend a cardiac transplant, should not be based on PET findings alone. The reversibility of segmental systolic dysfunction as predicted with Fludeoxyglucose F 18 PET imaging depends on success-
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