^{67}Ga Scintigraphy
Procedure Guidelines For Tumour Imaging

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Aim

The aim of this document is to provide general information about ^{67}Ga scintigraphy in oncology. This guideline should not be taken as definitive for all possible ^{67}Ga procedures or exclusive of other nuclear medicine procedures useful to obtain comparable results. It is important to remember that the resources and facilities available for patient care may vary from one country to another and from one medical institution to another. The present guide has been prepared for nuclear medicine physicians and intends to offer assistance in optimising the diagnostic information that can be obtained from ^{67}Ga gallium scintigraphy. The existing guidelines of the Society of Nuclear Medicine (SNM) have been reviewed and integrated with the present text. The same has been done with the most relevant literature on this topic, and the final result has been discussed by a group of distinguished experts.

Background

^{67}Ga has been used for imaging a variety of solid tumours since 1969. ^{67}Ga is cyclotron produced and supplied in an isotonic sterile non pyrogenic solution for i.v. administration. Generally it reacts with citric acid to ^{67}Ga citrate, which is the commonly employed form in nuclear medicine. ^{67}Ga imaging of neoplastic disease has shown the greatest utility in imaging lymphomas but it can also be used for other tumours. There is general agreement that ^{67}Ga is useful in the management of patients with lymphoma.

In addition, ^{67}Ga has been employed to detect chronic infections (such as sarcoidosis), to evaluate interstitial lung disease, and to examine patients with acquired immunodeficiency syndrome (AIDS).

Clinical usefulness of ^{67}Ga has been suggested for the study of adults presenting with fever of unknown origin because of the possibility of locating pathological uptake (both malignant and benign).

Indications in oncology

1) The main indication for ^{67}Ga scintigraphy is lymphoma (Hodgkin's disease, HD, and non-Hodgkin's lymphoma, NHL).
   1.1 In HD ^{67}Ga can be employed a) for evaluation of response to treatment: ^{67}Ga scintigraphy accurately assesses tumour viability in the presence of post-therapy residual disease detected by conventional radiological tools such as CT or MRI; b) as a prognostic indicator in the prediction of outcome; c) for evaluation of disease extent. The accuracy of ^{67}Ga scan is not superior to that of CT or MRI in staging lymphomas at presentation; however, it may be useful prior to therapy as a reference for treatment monitoring. ^{67}Ga is more effective in restaging because of the frequent presence of anatomical distortions/alterations following treatment.
   1.2 In NHL ^{67}Ga is can be used for the same purposes as in HD. The nuclear medicine physician should be aware that ^{67}Ga uptake correlates with tumour cell type and proliferation rate. High ^{67}Ga avidity is shown by diffuse large cell lymphomas including diffuse histiocytic lymphoma and poorly differentiated lymphocytic lymphoma. Similar ^{67}Ga avidity is shown by high-grade and intermediate-grade lymphomas including Burkitt's lymphoma. ^{67}Ga avidity in low-grade lymphomas (e.g. well-differentiated lymphocytic lymphoma) seems to be low but this is currently under debate. In fact, some investigators have found that low-grade lymphomas are able to take up ^{67}Ga. For these reasons a gallium scan is necessary before therapy in untreated patients in order to evaluate whether lymphoma is gallium avid or not. If the ^{67}Ga scan is negative, it should not be repeated.
2) The following non-lymphomatous tumours show ^{67}Ga avidity, but the usefulness of ^{67}Ga scanning in these patients has not been clearly demonstrated and for this reason it is not taken into account in the present guideline. ^{67}Ga scanning can be employed to image lung cancer, head and neck tumours, hepatocellular carcinoma, germ cell tumours, neuroblastoma, sarcoma, multiple myeloma, and melanoma.
3) ^{67}Ga is indicated for the examination of adults presenting with fever of unknown origin because of the possibility to locate pathological uptake (both malignant and benign).

Precautions

- Pregnancy (suspected or confirmed). In the case of a diagnostic procedure in a patient who is known or suspected to be pregnant, a clinical decision is necessary to consider the benefits against the possible harm of carrying out any procedure.
- Breast feeding (breastfeeding should be discontinued)
- Children aged less than 14 years (due to the high radiation exposure children should not undergo ^{67}Ga scintigraphy except when there is clear evidence of malignancy).

Pre-examination procedures

1) Patient preparation

The technologist or physician should give the patient a thorough explanation of the examination.
Food and liquid restrictions are not mandatory. Bowel preparation is optional. In patients with constipation oral laxatives prior to imaging may decrease the activity in the bowel. In this case Laxatives should be given on the day before ^{67}Ga scintigraphy (at least 18 hours prior to scanning). Gallium scan should be avoided within 24 hr after blood transfusion or gadolinium-enhanced MRI scanning, which may interfere with 67Ga biodistribution. Also it is advisable to wait 3-4 weeks after chemotherapy for following-up imaging.

2) Pre-injection

A relevant history of the patient and physical examination are prerequisites to ^{67}Ga tumour imaging. The nuclear medicine physician should collect all relevant pathological, radiological and laboratory data.
Specific attention should be directed to:

- tumour cell type, grade, size and location
- degree of transferrin saturation (e.g. haemolysis or recent transfusion)
- interfering drugs including recent chemotherapy with iron preparations, chelation therapy, steroids, antibiotics and growth factors, or recent MRI with gadolinium contrast agent
- recent surgery, radiotherapy, diagnostic procedures, or trauma
- presence of inflammatory lesions or infectious processes
- renal and intestinal function
- presence of any anatomical, functional or pathophysiological abnormalities (such as diverticulum of the bladder, previous bowel surgery).

3) ^{67}Ga injection, dosage and administration

The activity of radiopharmaceutical to be administered should be determined after taking account of the European Atomic Energy Community Treaty, and in particular article 31, which has been adopted by the Council of the European Union (Directive 97/43/EURATOM). This Directive supplements Directive 96/29/EURATOM and guarantees health protection of individuals with respect to the dangers of ionising radiation in the context of medical exposures. According to this Directive, Member States are required to bring into force such regulations as may be necessary to comply with the Directive. One of the criteria is the designation of Diagnostic Reference Levels (DRL) for radiopharmaceuticals; these are defined as *levels of activity for groups of standard-sized patients and for broadly defined types of equipment.* It is expected that these levels will not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied. For the aforementioned reasons the following activity for ^{67}Ga citrate should be considered only a general indication, based on the data of the literature and the current experience. However, it should be noted that in each country nuclear medicine physicians should respect the DRLs and the rules stated by the local law. Injection of activities greater than national DRLs should be justified.
^{67}Ga citrate should be administered by i.v. injection. The activity should be 185 MBq (5 mCi) in adults and 3.7-7.4 MBq/kg (0.1-0.2 mCi/kg) in children. The organ which receives the largest radiation dose is bone surface (see Table).

Physiological ^{67}Ga distribution

About 10-15% (up to 25%) of the injected activity is excreted by the kidneys during the first 24 hours following injection. Subsequently, the main route of excretion is via the bowel. By 48 hours

after injection about 75% of the dose remains in the body and is distributed among the liver, bone, bone marrow, and soft tissues.
The normal distribution is variable and also includes nasopharyngeal, lacrimal, salivary, breast (especially lactating or stimulated), thymus and spleen.
The most important mechanism of cell uptake of ^{67}Ga appears to correlate with the presence of the transferrin receptor CD71, which may be a marker of gallium avidity. Lactoferrin also binds ^{67}Ga.

Radiation dosimetry
The estimated absorbed radiation dose to various organs in healthy subjects following administration of ^{67}Ga citrate is given in the Table. The data are quoted from ICRP no. 80.

	Absorbed dose per unit activity administered (mGy/MBq)		
Organ	**Adult**	**15 years**	**5 years**
Adrenals	0.13	0.18	0.36
Bladder	0.081	0.11	0.20
Bone surfaces	0.63	0.81	2.2
Brain	0.057	0.072	0.19
Breast	0.047	0.061	0.15
Gall bladder	0.082	0.11	0.25
Stomach	0.069	0.090	0.21
Small instestine	0.059	0.074	0.16
Colon	0.16	0.20	0.54
Heart	0.069	0.089	0.21
Kidneys	0.12	0.14	0.29
Liver	0.12	0.15	0.33
Lungs	0.063	0.083	0.19
Muscles	0.060	0.076	0.18
Oesophagus	0.061	0.079	0.19
Ovaries	0.082	0.11	0.24
Pancreas	0.081	0.10	0.24
Red marrow	0.21	0.38	0.71
Skin	0.045	0.057	0.15
Spleen	0.14	0.20	0.48
Testes	0.056	0.072	0.18
Thymus	0.061	0.079	0.19
Thyroid	0.062	0.080	0.20
Uterus	0.076	0.097	0.23
Remaining organs	0.061	0.078	0.19
Effective dose (mSv/MBq)	**0.10**	**0.13**	**0.33**

Radiopharmaceutical: Gallium [^{67}Ga] citrate

Description
Gallium-67 is produced on an industrial cyclotron and provided in the form of a sterile solution of gallium citrate.

Preparation
No additional preparation is required by the end-user

Quality control
The radioactive concentration should be determined by measuring the activity of the vial in a calibrated ionisation chamber. Radiochemical purity analysis is not normally required but if desired a TLC method can be used. (Solid-phase ITLC, mobile-phase methanol; acetic acid (9:1), Rf Gallium(III) 0.0).

Special precautions.
The preparation may be diluted with sterile physiological saline if required.

Gamma camera quality control
Quality control of the gamma camera and image display should be routinely performed according to the rules of the individual countries.
Demonstration of spatial registration in multiple energy windows may be required to optimise image quality.

Image acquisition
1) Instrumentation
The gamma camera for whole body imaging should be a large-field-of-view gamma camera equipped with a medium-energy (preferred) or high-energy collimator.
For SPECT imaging a rotating two or three-headed gamma camera is preferred.
A computer with SPECT software is necessary. Energy windows should be three windows over the main photopeak (93, 185 and 300 keV).

2) Acquisition modality
Initial images are obtained at 48 hours post-injection with the patient in the supine position.
Delayed images, at least 72 hours and up to 5 days after injection may be needed to differentiate normal colonic activity from lesions in the abdomen (this allows clearance of non-specific activity from the body and enhanced target to background in the images).
For whole body imaging anterior and posterior views are necessary. A scanning speed to achieve information density greater than 450 counts/cm^2 or greater than 1,500,000 counts for each view is suggested (matrix 256x1024).
Typical imaging times are 10 to 20 minutes per view. For planar images (matrix 256x256) of the chest it is desirable to have at least 2,000,000 counts, while spot views of the abdomen and pelvis should be acquired for 1,500,000 counts. Special attention should be paid to acquiring the chest and pelvic views without the liver in the field of view.
SPECT should be used routinely for studies in presence of ambiguous results and areas of uncertainty from planar images (mainly in the chest and abdomen). The importance of SPECT is emphasised as the reconstruction of multiple planes is critical in assessing subtle lesions in the chest and abdomen. Image acquisition parameters are 64x64 matrix, 30-40 seconds/frame, 360°.

Image processing
In case of SPECT one should take into account the different types of gamma camera and software available. Careful choice of image processing parameters should be adopted in order to optimize the quality of imaging.

Interpretation criteria
To evaluate ^{67}Ga images, the following items should be taken into consideration:
- clinical issue raised in the request for ^{67}Ga imaging
- clinical history of the patient
- knowledge of the physiological distribution of activity in liver, spleen, bone marrow, bone, gut, soft tissues and glandular tissues (lacrimal, salivary, nasopharyngeal and mammary)
- anatomical localisation of the uptake according to other imaging data
- intensity of the ^{67}Ga uptake; quantitative interpretative criteria to distinguish benign from malignant aetiology of hilar uptake have been proposed by some authors
- clinical correlation with any other data from previous clinical, biochemical and morphological examinations
- causes of false negative results (lesion size, recent iron or gadolinium administration)
- causes of false positive results (sites of physiological uptake, benign processes, chemo/radiotherapy-induced uptakes, recent surgery, recent administration of antibiotics or CSGF, external superficial contamination, renal failure)
- the use of ^{210}Tl chloride or ^{99m}Tc-MIBI in the differential diagnosis of thymic hyperplasia after chemotherapy in children has been suggested.

Reporting

The nuclear medicine physician should record all information regarding the patient, type of examination, date, radiopharmaceutical (administered activity and route), concise patient history, results of other diagnostic laboratory and instrumental tests, and the clinical question.

The report for the referring physician should describe:

-whether the distribution of ^{67}Ga is physiological

-findings of all areas of abnormal uptake

-topographic location of the lesion(s); uptake intensity

-correlation with other imaging modalities and clinical history

-interpretation: a clear diagnosis should be made if possible (artefactual uptake, benign, inflammatory or malignant lesion) accompanied by a differential diagnosis when appropriate.

In case the conclusive impression should need additional diagnostic studies or an adequate follow-up, this must be recommended.

Sources of error

- Patient motion.
- Misinterpretation of physiological uptakes (e.g. visualisation of the nipples and breasts).
- Prominent sternal uptake may be seen; this may mimic abnormal uptake in the mediastinum.
- Residual bowel activity may be mistaken for disease or obscure underlying lesions in the abdomen.
- Faint pulmonary hilar uptake may be seen in adult patients, especially in heavy smokers.
- Pulmonary hilar uptake may occur following chemotherapy (bleomycin, nitrofurantoin, cyclophosphamide, methotrexate, busulfan, vincristine, procarbamide, amiodarone) and radiation therapy.
- Thymic hyperplasia may be visualised after chemotherapy as a rebound response.
- Recent chemotherapy. ^{67}Ga scan should be performed prior to induction chemotherapy or at least 28 days after the last course of chemotherapy.
- Recent radiotherapy may affect ^{67}Ga uptake. Even if no univocal response of ^{67}Ga uptake has been shown after radiotherapy, ^{67}Ga studies should be performed at least 3-4 weeks after the last course.
- Bone uptake may be seen following administration of CSGF.
- Gadolinium EDTA for MRI contrast enhancement sometimes decreases ^{67}Ga uptake when given within 24 hours of injection.
- Iron administration may alter the biodistribution of ^{67}Ga by competing for transferrin receptor sites in plasma and tissue.
- Bone marrow harvest may cause uptake at the site of the procedure.
- Recent surgical incisions may cause ^{67}Ga uptake lasting several weeks.
- Increased activity may be present in patients with renal failure.
- Increased ^{67}Ga activity may be present when ^{67}Ga citrate has been administered in conjunction with certain antibiotics (clindamycin).

Issues requiring further clarification

1) Should ^{67}Ga scan be included in the routine for the initial staging of all patients with lymphomas or may play a complementary role to conventional imaging only in selected cases when a precise stage definition is crucial for risk assignment?
2) Should ^{67}Ga scan be used systematically in assessing the response of lymphoma to treatment or may be considered only in cases presenting with high-risk HD and NHL, to identify those patients in whom more aggressive approaches are required?
3) Recently ^{18}F-FDG PET has been shown to be highly accurate in the detection of both HD and NHL. Many investigators use PET for staging of lymphoma patients, determining residual tumour and studying tumour viability. Furthermore, the quality of FDG-PET imaging is much better than that of ^{67}Ga. On the basis of the clinical results it is to be expected that lymphomas will become one of the most common indications for PET in the future. In this context a number of issues should be clarified:

   -Has ^{67}Ga scan still a role in the diagnosis and management of lymphomas, in comparison to ^{18}F-FDG PET?

-Is ^{18}F-FDG only a more reliable alternative to ^{67}Ga scan, or should ^{18}F-FDG PET definitively substitute ^{67}Ga scan?
-If so, should ^{18}F-FDG PET substitute ^{67}Ga scan for all or only some indications (low-grade lymphomas, detection of skeletal and bone marrow lesions, diagnosis of abdominal masses, etc.)?

Disclaimer

The European Association has written and approved guidelines to promote the use of nuclear medicine procedures with high quality. These general recommendations cannot be applied to all patients in all practice settings. The guidelines should not be deemed inclusive of all proper procedures and exclusive of other procedures reasonably directed to obtaining the same results. The spectrum of patients seen in a specialised practice setting may be different than the spectrum usually seen in a more general setting. The appropriateness of a procedure will depend in part on the prevalence of disease in the patient population. In addition, resource available for patient care may vary greatly from one European country or one medical facility to another. For these reasons, guidelines cannot be rigidly applied.

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