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REVIEW

Regulatory and clinical implications of using diagnostic CT in PET/CT

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Abstract
The introduction of combined positron emission tomography (PET) and computed tomography (CT) scanner has made it possible to acquire, in a single study, complementary morpho-structural and functional/metabolic information. In its standard applications hybrid PET/CT imaging, with a low-dose (LD) CT scan without contrast medium administration, can allow attenuation correction and anatomical cross-sectional of functional PET images, while avoiding the increased radiation burden which, instead, is associated with a full-dose (FD) CT. Nevertheless, the association of PET imaging with FDCT and with contrast-enhanced (CE) CT, i.e. diagnostic CT, has been investigated to increase the diagnostic accuracy of PET/CT in some specific clinical scenarios. There are potential clinical and procedural benefits to using single step combined dual imaging PET and FD-CECT. However, radiation protection regulations, guidelines from scientific societies, local provisions, correct clinical decision making and practical considerations, limit the use of PET/CECT to selected patients in which a clinical or procedural justification must be demonstrated, despite current scientific context where there is a lack of significant studies that support its appropriateness.

Keywords PET/CT · FDG · Imaging procedure · Tumor · Oncology

Molecular imaging with positron emission tomography

The introduction of combined positron emission tomography (PET) and computed tomography (CT) scanner has made it possible to acquire, in a single study, complementary morpho-structural and functional/metabolic information. A significant increase in the diagnostic accuracy in malignant diseases has followed, such as in terms of staging and in the response assessment to treatment. In its standard applications hybrid PET/CT imaging, with a low-dose (LD) CT scan without contrast medium administration, can allow attenuation correction (AC) and anatomical cross-sectional of functional PET images, while avoiding the increased radiation burden which, instead, is associated with a "full-dose" CT. Nevertheless, the association of PET imaging with full-dose (FD) CT and with contrast-enhanced (CE) CT, i.e. diagnostic CT, has been investigated in the hope to increase the diagnostic accuracy of PET/CT in some specific clinical scenarios. An English literature search was performed using the PubMed and Embase databases using the following key words: "positron emission tomography (OR PET) and computed tomography (OR CT), contrast-enhanced PET/CT, full-dose PET/CT, unenhanced PET/CT, one-shot PET".

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Table 1 Concerns regarding the routine use of PET/CT by full-dose or CECT

Source and scope	Statements and sentence	
International scientific Guidelines	Standard PET/CT protocol includes low-dose CT scanning for CT-AC and anatomical correlation, CT scan parameters should be chosen such that patient exposure is minimized, yet dose is adequate to obtain the necessary diagnostic information	In the same subject, the same protocol should be followed at all subsequent imaging time points For these types of CT examinations, specific national or local dose limits must always be respected
Regulatory framework for radiation protection (ICRP and D.L 101/2020)	Medical exposures must be preliminarily justified and must demonstrate a sufficient net benefit Prescribing and specialist physicians to avoid unnecessary exposures make use of the previous diagnostic information	Doses must be kept at the lowest level compatible with diagnostic information Prescribing physician and specialist, have joint responsibilities in providing adequate information on risks and benefits to patients and companions
Local current provisions (i.e. Campania region)	High dose-CECT scan concurrently or within the 7 days before/after PET/CT are not recognized or reimbursed	For joint performance, PET/CT physicians under their direct own responsibility will note the precise reference of the clinical literature
Clinical pathways implications	Precision medicine provides personalized diagnostic tests pathways for each patient, a critical point in the clinical decision-making process Dual PET/diagnostic CT scan prevents the clinical information from the first exam necessary for a reasoned evaluation of the appropriateness of the second	Diagnostic accuracy of a test depends on the procedures already performed (pretest probability) that define the appropriateness of a diagnostic sequence Dual imaging may produce redundant or misleading information, with risk of overdiagnosis/overtreatment, in addition to consuming economic resources and further radiation exposure

Table 2 Summary of published data on PET/CT parameters and patient effective dose for ^{18}F-FDG whole body oncological studies

Reference	Scan length	CT description	Effective dose-CT (mSv)
Quinn et al. [3]	Base skull-mid-thigh	LDCT	5.0 ± 1.0
		FDCT	15.4 ± 5.0
Brix et al. [4]	Whole-body	LDCT	1.3–4.5
		CECT	14.1–18.6
Kaushik et al. [5]	Base skull-mid-thigh	LDCT	7.5
		FDCT	10.9–13.2

CT protocols for PET/CT imaging in the EANM guidelines

Within the framework of ^{18}F-fluorodeoxyglucose (FDG) PET/CT studies, procedural guidelines address different CT imaging modalities. In general, PET/CT is performed using a protocol comprising a scout scan and a LDCT scan for CT-AC and anatomical correlation. This typical PET/CT study meets the goal of obtaining the necessary diagnostic information while minimizing patient exposure [1]. If appropriate, a diagnostic CT scan, i.e. with full-dose and/or intravenous contrast enhanced agent, may be performed for regions of the body, by different PET/CT acquisition sequences or strategies [1].

High intravenous concentrations of contrast agent may cause artefacts in the reconstructed PET images and affect standardized uptake value (SUV) quantification. If quantization is not the main goal, this impact is considered acceptable only when CT data are collected in the equilibrium or venous phase, whereas arterial acquisitions should be avoided [1]. Moreover, deep inspiration for chest CT acquisition, if replaces the LDCT scan (with normal breathing), will cause a large degree of misregistration and may introduce unacceptable artefacts. Most importantly, in the same subject, the same protocol approach should be followed at all subsequent imaging time points [1].

Specific local or national dose limits may apply for these types of CT examinations and should always be adhered to. Overall, CT scan parameters should be chosen such that patient exposure is minimized, yet dose is adequate to obtain the necessary diagnostic information. Therefore, performing routinely a diagnostic PET/CT study, by a FD or CE scan, deserves some concerns considering clinical appropriateness, radiation protection regulatory context and local/regional current provisions (Table 1).

In a standard PET/CT, the contribution of CT on total effective dose outperforms PET, being 54–81% [2]. The effective dose related to CT varies significantly in relation to specific factors such as study protocol, tomograph, dose reduction algorithms, scan length. The effective dose of CT ranges from 1 to 20 mSv, generally 1–10 mSv for a LDCT and 10–20 mSv for a FD-CECT [3–5] (Table 2). Exposition due both CT and PET may lead to a substantial cumulative effective dose, e.g. ≥100 mSv [6]. At this level many organs might receive doses of ≥100 mGy, a range at which a statistically significant excess of certain cancers [7]. Since the largest radiation sources is CT, high dose protocol must be

accurately justified. In the Italian National Health Service LDCT scan is included in the PET/CT fee, therefore it does not constitute an additional cost, whereas a FD-CECT for oncological staging with at least three districts, has a cost of 327 euros.

Regulatory framework for radiation protection

The International Commission on Radiological Protection (ICRP) system of radiological protection is based on three fundamental principles: justification, optimization and the dose limitation of radiation exposure. In Italy the Legislative Decree (LD) 101/2020, implementation of Directive 2013/59/Euratom, establishes safety standards to protect people from the dangers arising from ionizing radiation. This DL has strengthened some aspects such as the doses delivered (LDR) and their periodic review, the joint responsibilities of the prescribing physician and the specialists, the adequate information to be given to patients and companions on the risks and benefits, the regulatory obligation to indicate the information relating to exposure on the report (dose class I-IV).

Some contents of articles 157–159 of LD, consistent with this topic, are summarized below:

- Art. 157: unjustified exposure is prohibited. All individual medical exposures must be preliminarily justified and must demonstrate a sufficient net benefit. The prescribing physician and the specialist physician, to avoid unnecessary exposures, make use of the information acquired or ensure that they are not able to obtain previous diagnostic information;
- Art. 158 (optimization): all doses due to medical exposures must be kept at the lowest level reasonably achievable and compatible with achieving the required diagnostic information;
- Art. 159 All medical exposures are carried out under the clinical responsibility of the medical specialist, upon motivated request of the prescribing physician. The medical specialist is responsible for choosing the methodologies and techniques suitable for obtaining the greatest clinical benefit with the least individual detriment.

Failure to comply with these rules is punishable by arrest up to one year or fines up to 60.000 euros.

Local current provisions

In addition to national laws and European directives, there are current provisions in force at local/regional level. For example, in the Campania region there are provisions of administrative nature aimed at containing additional costs as well as prescriptive inappropriateness. These are contained in notes 0343046/2021 with the subject "Specialist Outpatient Assistance" in confirmation of DCA 71/2016 and DCA 5/2017. The Region required that the diagnostic CT scan prescribed and provided concurrently or within the 7 days before/after the PET/CT are not recognized or reimbursed. This does not open the way to the implementation of the combined dual imaging (PET and FD-CECT) for outpatients in public facilities and those accredited with the National Health Service. If there are conditions of need and emergency for joint performance, the prescribing doctor, or the specialist in the case of a "suggested" prescription, under his own responsibility will note the precise reference of the clinical literature. This, with particular regard to the efficacy, clinical need or indications, which lead to justifying, in a few days of each other, the diagnostic imaging at risk of inappropriateness and increased costs, in order to avoid incurring the sanctions provided for by article 2 DL 405/2001.

Accuracy and appropriateness between simplification and complexity

In modern medicine, two perspectives prevail that must necessarily find a synthesis in daily practice, thanks to the doctor capability to face every problem with intelligence, science and conscience. Personalized medicine is best expressed in nuclear medicine, capable of exploring, for each individual patient, different variables that characterize disease, thus allowing a precision medicine approach. On the other hand, we have available Guidelines, Consensus, Recommendations, which collect the evidence of scientific literature and experts, from which it is important to start and then shape them on the uniqueness of our patient. So, we must follow consciously the search for balance between the two poles, personalization and generalization, both decisive.

As well known, the diagnostic accuracy of a test depends on the clinical context and the procedures already performed. This translates into the definition of the pre-test probability, a decisive factor in establishing the appropriateness of a subsequent diagnostic investigation. Diagnostic tests are a critical point in the clinical decision-making process, with possible undesirable consequences, such as overdiagnosis and overtreatment, if used in an inappropriate pathway. Indeed, the use of a method in a context of inconsistent pre-test probability, in addition to influencing its sensitivity and specificity, tends to produce redundant if not misleading information, perhaps making further investigations necessary. All this produces, in addition to clinical effects, the result of contributing to consuming the already

limited economic resources available. To this must be added the possible exposure to ionizing radiation.

In the standard path of diagnostic imaging, the morpho-structural evaluation, generally carried out with FD-CECT scan, usually precedes the metabolic PET one. This allows the second examination, typically PET, to be reserved for cases in which it is truly necessary and appropriate. Negative or frankly positive pictures (e.g. stage 4 disease) may not require further assessments, especially if they have a high radiation and economic impact. On the other hand, in some clinical contexts such as lymphoma, it has been highlighted that a standard PET/LDCT should be performed as first-line imaging procedure, also in patients with prevalent abdominal and pelvic involvement, limiting the acquisition of CECT in selected cases. This tailored approach would contribute to avoid useless radiation exposure and preserve renal function of patients [8].

Without a careful evaluation of the clinical indications, the joint execution of a PET study with a diagnostic CT (FD and/or CECT), whereas for routine PET a LDCT is sufficient, risks being an ineffective procedure, not clinically appropriate and therefore not justified. In particular, the legislator has underlined the importance, in order to avoid unnecessary exposure to ionizing radiation, that the physician makes use of all the information potentially available before a new exposure. It is clear that the combined execution of a PET/diagnostic CT scan prevents the acquisition of the clinical information from the first exam necessary for a reasoned evaluation of the appropriateness of the second. This would result in failure to comply with the principles of justification and optimization established by ICRP. It follows that PET/CECT is a procedure to be reserved for carefully selected cases where there is a clinical peculiarity or a procedural need. In these, justification, optimization and appropriateness are reflected in the specific need, evaluated the prescribing physicians and specialists, to personalize the diagnostic pathway of that specific patient, in addition to on the basis of evidence present in the scientific literature.

Role of diagnostic CT combined with PET

Although PET/CECT imaging is largely used worldwide there is a lack of large prospective trials on systematic application of dual-mode imaging by diagnostic CT and PET [9]. Morbelli et al. evaluated the added value of CECT in comparison to standard, non-enhanced CT in the context of PET/CT examination [4]. This analysis does not support the routine use of PET/CECT, confirming that PET/CT executed with LDCT is adequate for the workup of FDG-avid tumors [10, 11]. The use of CECT could improve the diagnostic potential of hybrid imaging in specific clinical scenarios such as in patients affected by head and neck or gastrointestinal cancer, and patients undergoing PET/CT for evaluation of abdominal lesions and for restaging purposes. These patients have to be specifically identified in the context of oncologic, multidisciplinary, disease-management team [10].

There are several reports of the possible superiority of PET/CECT over standard PET/CT in different clinical settings, including staging, restaging, presurgical evaluation and treatment planning of different tumor types such as in non-small cell lung, gastro-intestinal, liver, pancreas, uterus and ovary, lymphoma [12–19].

The added value of PET/CECT has been demonstrated in a specific population of patients affected with paraneoplastic neurological syndromes, a rare group of disorders that occur in less than 1% of cancer patients. In these patients, no malignant findings were detected by CECT alone, but when complementary to metabolic imaging the CECT component improved the detection of inconclusive lesions at PET, thanks to the evidence of anatomical lesions localization in regions of complex anatomy such as the head and neck region and within the abdomen and pelvis [20]. In this last anatomical district, in a population of ovarian carcinoma patients, it has been observed that PET/CECT could be relevant if able to induce a change of management, such as in case of a false-positive peritoneal finding in PET/LDCT or by showing the presence of active disease that was unmasked by PET/CECT. However, the lack of clear indications on the superiority of PET/CECT in terms of sensitivity, specificity, or accuracy does not support its routine use. Accordingly, the application of PET/CECT could be decided on a case-by-case basis, according to the principle of personalized medicine [21].

It is well established that diagnostic CT is an essential frontline investigation, however we are not discussing the role of diagnostic CT, but rather the need to perform CECT at the same time as the PET/CT study. The decisive diagnostic power of the CECT is such even if done preliminarily to the PET exam. Even assuming the necessity to fuse the CECT with PET imaging, element to be demonstrated, this is possible with many workstations and several freeware software programs. To our knowledge there is no significant scientific evidence that demonstrated a different diagnostic accuracy of combined PET/CECT obtained in a single session with respect to a preliminary CECT followed by PET, or the off-line image fusion of PET images with a recently obtained CECT scan.

In some experiences, the costs of performing both studies in a single session was lower than independent sessions, both for institution and for patient [22]. Yet, in this investigation the impact on the clinical management of oncological patients were not considered. The data only considers the cost analysis of two different organizational methods,

Table 3 Clinical scenario with added value of PET/CECT

Authors	Oncology area	Conclusions
Morbelli et al. [4]	Head and neck and gastrointestinal tumors restaging	Patient selection for PET/CECT should not be driven solely by mere tumor classification but should also account for the clinical question and the anatomical location of the neoplastic disease, which can significantly impact patient management
Pfannenberg et al. [6]	Non-small cell lung cancer	PET/CECT more accurately assesses TNM stage and radiotherapy planning
Nanni et al. [7]	Lung cancer staging and restaging	PET/CECT provides an optimal sensitivity in these patients, lack of histological diagnosis of cancer due to possible false positivity of the two methods, significantly reduces specificity
Tateishi et al. [8]	Rectal cancer nodal staging	PET/CECT is superior to non-enhanced PET/CT for precise definition of regional nodal status in rectal cancer patients
Rodríguez-Vigil et al. [9]	Lymphoma	Good correlation between PET/LDCT and PET/CECT
Strobel et al. [10]	Pancreatic cancer resectability	PET/CECT is feasible and more accurate than PET alone for assessing resectability
Kitajima et al. [11]	Ovarian cancer recurrence	PET/CECT is accurate for assessing recurrence and changes after therapy
Massollo et al. [15]	Ovarian carcinoma recurrence	PET/CECT does not perform better than PET/LDCT but can occasionally clarify doubtful peritoneal findings on PET/LDCT
Kitajima et al. [12]	Uterine cancer recurrence	PET/CECT is accurate for assessment of uterine cancer recurrence and its use reduces the frequency of equivocal interpretations
Schramm et al. [14]	Paraneoplastic neurological syndromes	PET/CECT exhibits improved detection of underlying malignancy vs. CECT alone
Pfluger et al. [17]	Malignant melanoma staging	It is justified to perform PET/LDCT instead of PET/CECT

which both required the necessity to perform both services, neglecting the possibility that after the first test the second could be avoided, with a consequent not insignificant saving.

Clinical implications

Diagnostic CECT scan is an indispensable tool in many clinical scenarios, particularly in oncology (Table 3). This essential first step investigation allows for morpho-structural information that may require subsequent metabolic and functional characterization provided by PET.

Performing PET/CT and CECT in a single step undoubtedly has some advantages. These are linked to the reduction of waiting list and timing of one-stop-shop versus two separate procedures, to the possible better patient compliance, to potential institutional cost-saving. These advantages exist only where, for a specific diagnostic pathway assessed individually on the single patient, the execution of the PET imaging is considered necessary and appropriate, regardless of the results of the CECT. Otherwise, its routine use, without clinical justification, produces not only a series of negative clinical and procedural effects, but also violates specific radiation protection regulations to reduce radiation burden, which are state law and are subject to significant sanctions. Regarding clinical decision-making process, an inappropriate sequence of tests may have undesirable consequences in terms of diagnostic accuracy, overdiagnosis and overtreatment, with an impact on health care costs. Finally, since guidelines state that the same patient should not have different approaches in all subsequent imaging time point, it would result in the need to constantly perform the CECT in every following checks, which should, however, as per the guidelines, be limited to a specific body area [1].

The rule on the "justification" process, which involves the prescriber and the specialist, is very specific and requires a preliminary evaluation from which a clear and demonstrable benefit arises, after evaluation of the previous investigations. There is also an obligation to give the patient and companions adequate information about the procedural choice and their risks and benefits.

In addition to national laws and European directives, local current provisions, such as in Campania Region, reinforce the concept of appropriateness. They require that prescribing physician or specialist note the precise reference of the clinical literature. The routine execution of the two tests (PET and diagnostic FD-CECT) at the same time prevents the evaluation of justification and creates the conditions for a questionable new PET/CT standard. This approach prevents a real personalization of the diagnostic pathway and tends to affirm the concept that the diagnostic content of the ordinary PET/LDCT exam is insufficient, where the Procedural Guidelines state the opposite [1, 19].

Furthermore, although potential savings are described, routinely performing FD-CECT in the workflow of a nuclear medicine department creates a series of adverse events that

burden an already complex procedure. The execution of the contrast medium lengthens the procedure times by subtracting machine time for other PET exams, especially where there is only one tomograph with possible effects on waiting lists of cancer patients. Furthermore, it is determined, a greater decay of the radiopharmaceutical with significant effects especially on the more expensive drugs. Finally, there are medico-legal implications related to the need for further justification for the potential adverse events of the contrast media.

Although there are many known clinical settings in which PET/CECT has demonstrated its efficacy, there is a lack of large clinical studies comparing its diagnostic accuracy values. Morbelli et al. has isolated only 4 out of 20 clinical areas, related tumor type, site of disease and clinical question, in which there is a statistically significant advantage adding CECT to PET/CT hybrid imaging [10]. This obviously does not mean that a better diagnostic accuracy has been demonstrated for combined PET and CECT obtained in a single session with respect to a preliminary CECT study followed by PET study, also considering the possibilities of off-line image fusion imaging. Moreover, in other clinical scenarios, such as melanoma, there is no justification for PET/CECT [23].

Conclusions

There are potential clinical and procedural benefits to using single step combined dual imaging PET and FD-CECT. However, radiation protection regulations, guidelines from scientific societies, local provisions, correct clinical decision making and practical considerations, limit the use of PET/CECT to selected patients in which a clinical or procedural justification must be demonstrated, despite current scientific context where there is a lack of significant studies that support its appropriateness.

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Declarations

Competing interests The authors declare no competing interests.

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