ORIGINAL ARTICLE

CLINICAL AUDIT OF A JOINT COMMISSION ACCREDITED PET/CT FACILITY IN PAKISTAN: STANDARDIZATION IS NEED NOT DESIRE

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PJR October - December 2016; 26(4): 268-274

ABSTRACT

AIM: Aga Khan University Hospital has recently embarked into PET/CT imaging and we have tailored standard operating procedures (SOP) as per recent guidelines. This clinical audit was done to ensure good clinical practice as per defined bench marks. **MATERIAL & METHODS:** This clinical audit was conducted from 1st July till 5th August 2016 and we did audit of 11 parameters related to demographics, patient preparation, acquisition protocol, qualitative and semiquantitative parameters, reporting and radiation dose from PET/CT study. The compliance of these parameters was checked against predefined benchmarks. **RESULTS:** 100% compliance was found for demographic, height and weight entries, fasting blood glucose level, pregnancy, intravenous contrast and low dose CT scan. Non-compliance was found for dose of ^{18}FDG (71% for 3 MBq/kg benchmark), uptake time (25% against 55-75 minute benchmark), mean hepatic uptake (19% against 1.3-3% benchmark) and addenda in reporting (4% against 0.5% benchmark). **CONCLUSIONS:** This clinical audit finds an over-all good compliance to departmental protocol which is tailored as per recent guidelines to achieve a global standardization in PET/CT imaging. Although radiation dose is significantly low, attempts should be taken to minimize the magnitude of non-compliance. Similarly, work flow must be strategized to prevent avoidable reasons resulting in non-compliance in uptake time.

Key Words: PET/CT; standardized; FDG Dose; Uptake Time; dosimetry; addendum

Introduction

In current era, Flourodeoxyglucose (^{18}FDG) based hybrid positron emission tomography and computerized tomography (PET/CT) has become an integral part of management of various cancers. Basic reason for this popularity is its high sensitivity, better specificity due to CT component and a high diagnostic accuracy. ^{18}FDG PET/CT provides high quality functional, anatomical and fused images depicting the presence and extent of a malignant process which is important for diagnosis, staging, restaging and response evaluation.[1] In addition, it also provides semiquantitative parameters like standardized uptake values (SUV; most commonly used is maximux SUV, i.e. SUV_{max}). These qualitative and semiquantitative parameters guide the treating medical and radiation oncologists about the selection and modification in management strategy and also precise delineation of metabolic tumor volume by radiation oncologists.[2]

^{18}FDG is a glucose analogue and its accumulation in tissue is proportional to the amount of glucose utilization by tumor cells having overexpression of the glucose transporter (GLUT) and increased hexo-

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Submitted 24 August 2016, Accepted 15 September 2016

kinase activity which incorporates it into the first step of the normal glycolytic pathway.[3] It is important to understand that ^{18}FDG uptake appreciable on images and estimated by SUV is dependent upon many confounding factors like tumor biology, injected dose of ^{18}FDG, duration of fasting, fasting blood glucose level, time between injection and imaging, use of intravenous and oral contrast, scanner sensitivity, reconstruction software, size of region of interest (ROI) drawn over lesions, tumor size and partial volume effect, etc.[4] Beyond any doubt these factors have a direct impact upon repeatability and reproducibility of ^{18}FDG PET/CT. This obviously poses a significant variability in interpretation of series of scans performed with different parameters with an expected variable SUV values. This is one of the sole reasons, why PERCIST (PETResponse Criteria in Solid Tumors) has not been well adopted worldwide since 2009. To address this issue, nuclear medicine and radiological societies in different parts of world have stressed upon a standardized imaging and interpretation protocols to ensure repeatability, reproducibility, precision and accuracy of PET/CT procedures performed at any imaging facility.[5]

Aga Khan University Hospital (AKUH) Karachi, Pakistan (only joint commission accredited healthcare facility of country) acquired PET/CT scanner and cyclotron in December 2015. Being cognizant of importance of repeatability, reproducibility, precision and accuracy, we adopted a standardized PET/CT protocol as recommended by Uniform Protocol for Imaging in Clinical Trial (UPICT) which was formulated by SNMMI, EANM and RSNA.[6]

Aim of this clinical audit was to find out the compliance of PET/CT imaging services of AKUH to its formulated protocols and standard operating procedures and observation of certain other important parameters.

Material and Methods

This clinical audit was conducted at PET/CT imaging services of Aga Khan University Hospital (AKUH) Karachi, Pakistan from 1st July till 5th August 2016. During the study period, we examined patient's record for following items.

Demographics: Mentioning of name, medical record number, accession number, age and gender as these parameters are one of the sentinel patient safety goals as per Joint Commission. The bench mark is 100% compliance.

Weight and Height: These parameters are required for calculation of SUV_{max} by computer software. The bench mark is 100% compliance.

Duration of Fasting and Fasting Blood Glucose Level: As per protocol patients are called with at least 4 hour of fasting (preferably 6 hours) for solid food and beverages (plain water is allowed for better hydration) to ensure low blood glucose and low serum insulin level as insulin is directly responsible for glucose uptake by non-tumour cells.[7] To ensure better uptake of radiolabeled glucose by tumor cells, FBS must be <200 mg/dl and test is rescheduled if it = 200 mg/dl.[8] The bench mark is 100% compliance.

Pregnancy: For female patients in their reproductive age, 10 day rule or in case of doubt a pregnancy test is performed to rule out the pregnancy. The bench mark is 100% compliance.

Oral and Intravenous Contrast: As per recommendation in recent guidelines,[8] intravenous contrast is not given and if requested by referring physician, a diagnostic CT scan with intravenous contrasts is done after completion of PET/CT scan. For better visualization of bowel, diluted oral gas-trografin (10 cc in 1 liter plain water) is given at least 1 hour prior the PET/CT imaging. A compliance of 100% was set as bench mark for intravenous contrast.

Uptake Time: It is defined as time between ^{18}FDG injection and imaging. There is a progressive uptake in tumor tissue with a significant impact upon estimated SUV values. As per department protocol, imaging must be performed within 55-75 minute and for follow up ±10 minutes of baseline study but not before 50 minute. 100% compliance was set as a bench mark.

Low Dose CT Protocol: CT component of PET/CT study, contributes more than 60% of effective radiation dose to patients which increases the life time attri-

butable risk (LAR) for second primary malignancy in these patients.[9] Based on these facts, recent EANM and UPICT guidelines do recommend use of low dose non-contrast enhanced CT for attenuation correction and anatomical mapping.[8] As per departmental protocol, we do PET/CT without intravenous contrast and in case it is required, than as a separate study after completion of PET/CT imaging. Effective dose from CT (External Exposure) was calculated by multiplying dose length product available on computer screen (DLP; mGy.cm) with ICRP conversion coefficient "k" 0.015 (mSv / (mG. cm)).[10]

Dose of ^{18}FDG (Internal Exposure): For same reason as mentioned above, the departmental protocol recommends to use 3 MBq /Kg of ^{18}FDG and effective dose imparted by was calculated by using coefficient 1.9 × 10-2 milli Sievert / Mega Becquerel (mSv/MBq) as per ICRP publication 106.[11]

Mean Hepatic Uptake (Hep SUV$_{mean}$): This parameter is a quality index of ^{18}FDG PET/CT study and we use a range 1.3 - 3.0 as suggested in recent guidelines.[8] Values beyond this range reflects incorrect FDG administration or technical issues and signifies that quantitative analysis must be used with caution.

Scan Findings: In this audit we also calculated the scans interpreted as negative (no hypermetabolic focus) or positive (having single or multiple hypermetabolic focus).

Addendum in Reporting: In this audit we also observed the frequency of addenda made in PET/CT reporting during study duration. There is no reported incidence of addenda in PET/CT. Based on a reported study which addressed frequency of addenda CT abdomen studies,[12] we selected a bench mark of <0.5% of total PET/CT reports.

Results (Tab. 1 & 2)

Demographics, Height and Weight: Total 110 patients were included during study period. All questionnaires were found to have correct addressograph and no incidence of wrong patient or wrong injection (i.e. medical event) was found. The mean age of the study cohort was 51 ± 20 years with a male: female ratio of 62%: 38%. The mean body mass index (BMI in Kg/m^2) was 23.80 ± 4.74. All patient's questionnaires were found to have demographic information with a compliance of 100%. Correct entries of height and weight are very important as it has an impact on SUV$_{max}$ calculation.

Variable	N = 110
Age (Median ± SD) years	51 ± 20
BMI (mean ± SD) Kg/m^2	23.80 ± 4.74
Male: Female	68:42 (62%: 38%)
FDG Dose (mean ± SD) MBq	195 ± 43
Uptake Time (mean ± SD) minutes	69 ± 12
FBS (mean ± SD) mg/dl	115 ± 26
CTDI (mean ± SD)	3.48 ± 1.11
DLP (mean ± SD) mGy.cm	386.18 ± 121.33
Effective Dose from CT (mean ± SD) mSv	5.79 ± 2.09
Hepatic uptake Hep SUVmean (mean ± SD)	1.70 ± 0.44
Positive: Negative scan	78 ± 32 (71%:29%)
Frequency of addendum	04% (04/110)

SD= Standard Deviation
BMI=Body Mass index
FDG= Flourodeoxyglucose
MBq=Mega Becquerel
FBS=Fasting Blood Sugar
CTDI=CT Dose Index
DLP=Dose Length Product
SUV=Standardized Uptake Value

Table 1: Patient's demographics

Variable	Beyond protocol	Within protocol	p value
FDG Dose in MBq ≤10% under dose	33 (30%)	32 (29%)	0.8711
FDG Dose in MBq ≥10% Over dose	45 (41%)		0.0627
Uptake Time <55 minutes	05 (4%)	82 (75%)	<0.0001*
Uptake Time >75 minutes	23 (21%)		<0.0001*
FBS ≥ 200 mg/dl	00 (0%)	110 (100%)	<0.0001*
Hepatic uptake Hep SUV^{mean} <1.3	21 (19%)	89 (81%)	<0.0001*
Hepatic uptake Hep SUV^{mean} >3.0	00 (0%)		<0.0001*
Number of Addendum	04 (04%)	106 (96%)	<0.0001*

*p<0.05

Table 2: Variation analysis in standardized protocol for FDG PET-CT studies

Duration of Fasting and Fasting Blood Glucose Level: In all patient's questionnaire duration of fasting

was found mentioned and no entry was found less than 4 hour fasting. Mean FBS was 115 ± 26 mg/dl. No patient was found to have FBS ≥ 200 mg/dl at the time of having ^{18}FDG injection (100% compliance with p-value <0.0001). Staff narrated that they are used to reschedule the patients if they are not adequately prepared although correct number patients rescheduled were not recorded.

Pregnancy: In 42 female participants, questions were asked about the possible pregnancy and no incidence of missed pregnancy was found.

Oral and Intravenous Contrast: Entries were made for oral contrast in 103 cases while 08 forms were found blank despite of administration of oral contrast. No PET/CT study was performed with IV contrast (100% compliance).

Uptake Time: The mean uptake time was found 69 ± 12 minute. In 82 patients (75%), uptake time was 55-75 minute (75% compliance against the benchmark of 100%). In 5 (4%) patients, study was acquired before 55 minute and in 23 (21%) uptake time was beyond 75 minute was observed (p-values <0.0001).

Low Dose CT Protocol: Using a low dose non-contrast enhanced protocol, the mean CT dose index (CTDI) was 3.48 ± 1.11 and dose length product (DLP in mGy.cm) was 386.18 ± 121.33 as demonstrated by computer screen. The mean effective dose from CT examination (external exposure) was 5.79 ± 2.09milliSievert (mSv).

Dose of ^{18}FDG (Internal Exposure): The mean dose of ^{18}FDG injected was 195 ± 43 MBq. As departmental protocol, 32 (29%) patients did receive the dose as per protocol (3 MBq/Kg) while under dose (≤10%) or over dose (≥10%) was seen in 33 (30%) and 45 (41%) of patients (non-significant p-values) (Fig. 1). The mean dose imparted by ^{18}FDG was 3.71 ± 0.82 mSV.

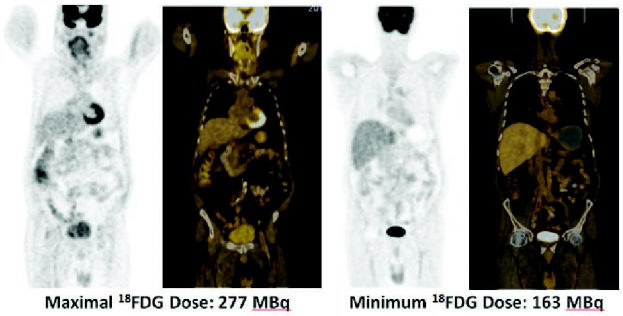

Figure 1: FDG PET and PET/CT images acquired with minimum and maximum injected doses of ^{18}FDG

Mean Hepatic Uptake (Hep SUV$_{mean}$): The mean value for this quality indicator in our cohort was 1.70 ± 0.44. In 89 (81%) patients it was within the benchmark of 1.3 -3.0. In 21 (19%) the Hep SUV$_{mean}$ value was <1.3 and no patient was found to have values >3.0 (Fig. 2).

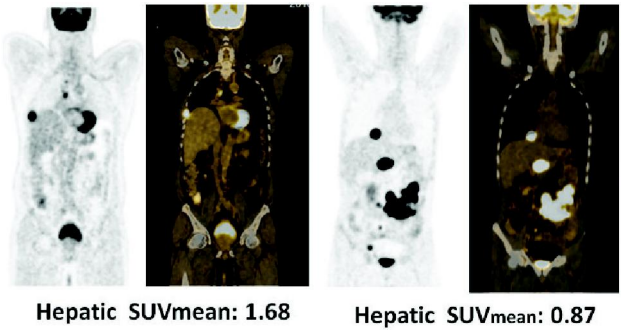

Figure 2: FDG PET and PET/CT images with Hepatic SUV$_{mean}$ within and below bench mark of 1.3 -3%.

Scan Findings: The scan was interpreted as positive for significant abnormality in 78 (71%) patients while in 32 (29%) scan was interpreted as negative.

Addendum in Reporting: The frequency of addendum in reporting was found in 4 (4%) against a bench mark of <0.5%.

Discussion

A clinical audit is an effective tool to improve the quality of patient care, experience and outcomes through review of systems, pathways and outcomes against set standards, and the implementation of changes in the system based on the derived results.[13] Comparing to research, audit has its focuses in management ensuring things are done right, while research encompass that science and academia discovering the right thing to do. PET/CT is the most sensitive hybrid imaging modality which provides high magnitude of functional and morphological information based on qualitative and semiquantitative parameters. Aga Khan University Hospital has recently embarked into PET/CT imaging and we have tailored standard operating procedures (SOP) as per recent guidelines.[8] This clinical audit was done to ensure good clinical practice as per defined bench marks.

Demographics, Height and Weight: We found 100% compliance regarding the addressograph, height and weight entries in patient's questionnaires. The basic reason is that we have a computerized registration system and system generates receipts with addressograph and pertinent indications and clinical information which is attached with a questionnaire. As per patient international safety goal standard, every patient is recognized by name and medical record number and attending nurse or technologist than takes the height and weight of the patients. History is taken by residents who ask 13 pertinent questions regarding diagnosis, h/o recent surgical or medical management, use of marrow stimulating agent and anti-diabetic treatment and findings of previous imaging. It is necessary to have correct entries of height and weight, as wrong entries would have an impact upon SUV_{max} values and may lead to wrong interpretation of PE/CT studies based on semiquantitative parameters.

Duration of Fasting and Fasting Blood Glucose Level: Lower levels of fasting serum glucose and insulin are one of factors ensuring the quality of PET images. In this clinical audit, we found 100% compliance which indicates a better communication between patient and booking person at reception and also with technologist who is checking the FBS. Rescheduling the patient was narrated but not recorded and we suggest record keeping of these would help to look into magnitude and possible reasons of such incidences.

Pregnancy: As per ICRP the radiation absorbed dose to non-gravid uterus is 1.8×10^{-2}mGy/MBq.[11] A radiation based procedure in a known or suspected pregnant could be performed if benefits outweighed the harm. However, in this clinical audit, all female participants confidently denied pregnancy. This shows a good counseling by staff or receptionist to the female patients who are in reproductive age group.

Oral and Intravenous Contrast: Use of intravenous contrast has a possibility of falsely high SUV_{max} and this poses problem as PERCIST or RECIST criteria are based on % change in these semiquantitative parameters. Therefore, to achieve a global standardized protocol in an attempt to use these interpretation criteria in a scrupulously way, recent guidelines don't recommend use of intravenous contrast.[8] We have found 100% compliance and shows good medical practice. However, in 08 patients questionnaire administration of oral contrast was found missing and which needs to be improved.

Uptake Time: Uptake of glucose (^{18}FGD) in malignant cell has temporal progression and PET/CT studies acquired at different uptake time in same patient, would be different qualitatively with different SUV_{max} values. For patients having a follow-up PET/CT scan with different uptake times of baseline and follow up studies, there is possibility of variable semiquantitative values which would be difficult to differentiate either secondary to tumor response to therapy or due to different uptake times between 02 studies. To minimize the impact of these variations, recent guidelines stress upon to acquire study within 55-75 minute (± 10 minute for follow up but not before 50 minute). We found a compliance of 75% while in 25% uptake time was beyond the recommended time. The most common reasons were directly related to patients like taking longer time in washroom, vomiting, low BP or uneasiness, hypoglycemia, etc. Other reason for this non-compliance were technical like error in scanner, acquisition of contrast enhanced CT after a non-enhanced PET/CT or time consumed for fitting radiation therapy devices for metabolic tumor marking on PET based treatment planning.

External (CT) and Internal (^{18}FDG) Radiation Dose: In all patients low dose CT protocol was used and the mean effective dose was 5.79 ± 2.09 mSv. However, for ^{18}FDG dose, compliance was observed in 29% cases. The primary reason for this non-compliance was the yield of ^{18}FDG per run of dose-on-demand cyclotron which is distributed in 2-4 patients. However, images of patients injected with highest and lowest ^{18}FDG doses were comparable and this is due to the Time-of-Flight scanner with a very low resolution time (<450 picosecond). The mean dose imparted by ^{18}FDG was 3.71 ± 0.82 mSV. The median effective dose from PET/CT study in our cohort was 8.85 mSv (range:5.56-13.00)[14] which is significantly lower than the reported lowest dose .

Mean Hepatic Uptake (Hep SUV_{mean}): According to recent studies, SUV_{max} could be used with certainties in studies having Hep SUV_{mean} between 1.3-3.0. In our audit, 81% of studies were found to have values within this range and signifying that semiquantitative parameters derived out could be used with high level of confidence. However, in 19% this parameter was below 1.3 and primary reason was inadequate injection technique resulting in either extravasation or hold up of fraction of ^{18}FDG in tubes. As per recent guidelines uncertainties related to this must be mentioned in report.[8] However, we did not find such pertinent statement in reports of these patients.

Scan Findings: As expected, majority of the scans were found positive and the primary reason is referral bias which means test was done in patients with known malignancy and not as a screening test for those suspected for malignancy.

Addendum in Reporting: During the study period the incidence of addendum in reporting was significantly high (4/110 patients). This is higher than reported incidence of 0.5% which is for CT based study.[12] The primary reason for this trend is that reporting radiologists are naïve in reporting PET/CT and we expect a declining trend with improving learning curve in days to come.

This clinical audit finds an over-all good compliance to departmental protocol which is tailored as per recent guidelines to achieve a global standardization in PET/CT imaging. Although radiation dose is significantly low, attempts should be taken to minimize the magnitude of non-compliance. Similarly, work flow must be strategized to prevent avoidable reasons resulting in non-compliance in uptake time.

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