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The role of triphasic CT imaging and 18F FDG PET CT on detection of extrahepatic metastases and proper staging of HCC: a comparative study

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Abstract

Background: Extrahepatic metastases and proper staging of HCC are mandatory for proper assessment of the disease process and its exact extent. Subsequently, clinicians can put precise management and treatment strategies for patients with metastatic HCC. 18FFDG PET/CT is one of the best imaging modalities for the proper detection of metastases and staging. It can provide both functional information and high contrast resolution of CT.

Results: On comparison between 18F FDG PET/CT and triphasic CT regarding metastases PET/CT showed greater sensitivity (92.3%) and specificity (84.4%), than triphasic CT (51.3%), (81/3%), and (76.9%), respectively. PET/CT revealed that the SUV max cutoff point for diagnosis of HCC was > 3.PET/CT revealed an SUV max cutoff point of > 5.57 for predicting that HCC has extrahepatic metastases. PET/CT revealed an SUV max cutoff point of > 3.35 for differentiating between metastatic and nonmetastatic lesions.

Conclusions: PET/CT combines the advantages of the excellent functional information provided by PET and the contrast resolution of CT. It increases the rate of detection of extrahepatic metastases, so it is more sensitive than triphasic CT in the staging of HCC. Using the standard uptake value proved to be efficient in HCC diagnosis and staging being more related to the functional activity of the tumor cells.

Keywords: 18F FDG PET/CT, Triphasic CT, HCC, Staging, Extrahepatic metastases, SUV

Background

Screening programs based on ultrasonography and α -fetoprotein (AFP) among high-risk patients can improve diagnosis and provide a more effective treatment of HCC. With progress in variable treatment modalities, the proper detection of HCC has been much improved. With the long survival of HCC patients, the frequency of extrahepatic metastases was described up to 42% of

patients. Exact assessment of extrahepatic metastases of HCC is vital since treatment modality can be modified according to their presence [1].

Sometimes traditional imaging modalities cannot adequately demonstrate the exact number of the metastases as the majority of removed metastases have been detailed and diagnosed to be up to 68% in biopsies. Metastases may, later, develop metachronous during treatment or after treatment. Tumor with aggressive behavior can attack nearby structures such as vessels or lymphatic channels and lead to inevitable metastatic illness to other organs or lymph nodes [2].

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Since positron emission tomography (PET) or PET-CT was presented to the oncologic setting, it has played vital parts in recognizing, precisely staging, and evaluating HCC. PET imaging visualizes tissue metabolic data that closely affect treatment [3].

PET-CT is an effective noninvasive imaging tool that can scan the whole body, so allow better detection of occult metastatic lesions and proper staging. Although triphasic CT is can offer anatomical and structural changes in metastatic lesions, PET-CT can offer more functional and metabolic changes that occurred before these structural changes, subsequently allows early detection of metastasis and proper staging of HCC. However, its low sensitivity still makes a diagnostic obstacle [3].

In our study, we assessed the diagnostic role of 18F-FDG PET/CT in comparison with triphasic CT for early detection of extrahepatic metastasis and proper staging of HCC. So, we can help clinicians to choose the best imaging modality for early diagnosis. Subsequently, they can establish a proper treatment plan.

Aim of the work

Our study aims to evaluate the role of 18-F FDG PET/CT in comparison with triphasic CT for better detection of extrahepatic metastases and proper staging of HCC.

Methods

Our prospective study included 40 patients with 56 lesions referred to the radiodiagnosis department of our institution for the staging of HCC. A triphasic CT and 18F FDG PET/CT assessment were done in our Nuclear Medicine Unit. The study was done in the period from October 2020 till October 2021. All the patients included in our study provided informed consent for our examinations. The privacy of patients was guaranteed throughout the different phases of the study. Full history taking and clinical examination were done. Our study included patients coming for staging who was diagnosed with HCC by clinical and radiological data (either by US, MRI, CT, or biopsy). Patients with contraindications to the Contrast agent, patients with uncontrolled DM, patients with a bad general condition needing life support, and patients with lesions smaller than 10 mm were excluded from our study. Patients were subjected to PET/CT study and triphasic CT after fasting for 6 h.

18F FDG PET/CT and triphasic CT were done using GE Discovery IQ PET/CT scanners for both studies. All patients were asked to fast for six hours earlier to the scan. All metallic materials on the patients were removed. Patients were inquired to evacuate their bladders. IV cannula was embedded within the patient's arm for administration of 18F FDG. The patients were taught to maintain a strategic distance from any kind of strenuous

movement sometime recently after the examination and taking after infusion of the radioisotope to stop physiologic muscle take-up of FDG. Serum glucose was routinely measured earlier to 18F FDG infusions, and fasting levels were 70–140 mg/dL.

A dose of 0.1 mCi/kg of 18F FDG IV injection 45–60 min before the examination was administered. The patients were positioned supine in a comfortable head fixation with arms up. Helical CT was performed following injection of about 125 mL of a non-iodinated CM at a 4 Ml/sec rate using a power injector. At first arterial phase abdomen, CT was acquired then the whole-body CT venous phase, then whole-body PET CT followed by finally the delayed phase abdomen CT.

Technique of PET/CT

For a typical whole-body PET/CT study (neck, chest, abdomen, and pelvis), scanning began at the skull base level and extended caudally to the level of the upper thighs. The total length of CT coverage was an integral number of bed positions scanned during the acquisition of PET data. The study was performed with the patient breathing quietly. Scanning parameters are collimation width of 5.0 mm, the pitch of 1.5, gantry rotation time of 0.8 s, and field of view of 50 cm. The helical data are retrospectively reconstructed at one-mm intervals. PET was performed following the CT study without moving the patient. Approximately 9- to 11-bed positions are planned in the three-dimensional acquisition mode for scanning the entire patient with 3–5 min acquisition at each bed position.

PET/CT Fusion: Hundreds of trans-axial PET and CT images were first reconstructed. These were then reformatted into coronal and sagittal images to facilitate image interpretation. For each of these sets of PET and CT images, corresponding fusion images, combining the two types of data, also were generated. The whole acquisition time for an integrated PET/CT scan was approximately 25–30 min. PET image datasets were reconstructed using CT data for attenuation correction and co-registered images were displayed using special software.

Technique of triphasic CT

Triphasic CT technique: multi-detector spiral CT used with scanning parameters 120 kVp, 180 MAs, 7-mm section collimation, and 7 mm/s table speed during a single breath-hold helical acquisition of 25–30 s, depending on liver size. Images were obtained in a craniocaudal direction and reconstructed every 7 mm to provide contiguous or overlapping sections. The patients were positioned supine, with arms up. A non-ionic iodinated CM according to the patient's weight was injected. The volume of CM delivered was 2 mL per kilogram. Each patient

received a CM (Ultravist 300) at a rate of 5 mL/s through an IV catheter by using a dual syringe power injector. a saline chaser was used by injection 40 cc after the injection of intravenous contrast material, the liver scanned at arterial phase (after 25–30 s delay) to obtain excellent hepatic arterial opacification with minimal contrast in the PV, portal venous phase (65–70 s delay) to show PV opacification, delayed phase (30 min delay) starting from the top of the liver to the bottom of the kidneys. The clinical history and medical sheets of all the patients were adequately and precisely reviewed.

Data analysis and interpretation

All triphasic CT examinations were analyzed by a consensus of two experienced observers of radiologists with ten years of experience in body imaging. The triphasic images were evaluated for the presence and extent of hepatic lesions and the presence of extrahepatic lesions.

All PET/CT examinations were analyzed by a consensus of two experienced nuclear medicine radiologists with 10 years of experience in PET/CT imaging. The PET images and the volume of CT scans were evaluated for the presence and extent of the 18 F-FDG -positive hepatic lesion and the presence of extrahepatic lesions. Abnormal 18 F-FDG uptakes were defined as radiotracer accumulation outside the normal anatomic structures and of greater intensity than background activity, excluding normal areas of physiological uptake. In all cases estimation of 18- FDG uptake was done using SUV max values for each hepatic mass and metastasis away from the liver. According to Barcelona clinic liver cancer (BCLC) staging, the staging was done.

Our gold standard of reference for metastatic lesions was the histopathologic examination or imaging follow-up and clinical assessment alongside the confirmation of diagnosis by other utilized modalities such as MRI. However, extrahepatic metastases were affirmed at first by radiologic implies and were checked at least 3 months after 18F-FDG PET/CT by follow-up imaging, counting chest CT, CT abdomen/ whole-body bone scan or MRI and whole-body bone scanning or MRI of bone.

Our gold standard of reference for the role of PET/CT in the detection of HCC was the triphasic CT.

Statistical analysis

The data were collected, revised, coded, and entered into the Statistical Package for Social Science (IBM SPSS) version 23. The quantitative data were presented as mean, standard deviations, and ranges when parametric and median, inter-quartile range (IQR) when data found nonparametric. Also, qualitative variables were presented as numbers and percentage. The comparison between groups with qualitative data was done by using the Chisquared test. The comparison between two groups with quantitative data and parametric distribution was done by using an independent t-test, while the comparison between two groups with quantitative data and nonparametric distribution was done by using the Mann-Whitney test. The receiver operating characteristic (ROC) curve was used in the quantitative form to determine the best cutoff point, sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and area under the curve (AUC) of the studied parameters to predict the value of PET per tumor.

The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p value was considered significant as the following: P > 0.05: Nonsignificant < 0.05: Significant < 0.01: Highly significant.

Results

Statistical analysis was performed for 40 patients. The study included 26 males (65%) and 14 females. The mean patient age is 63.10 ± 6.18 (54–75) years.

Our study included 40 patients with 56 lesions diagnosed as HCC. According to the diagnostic performance of PET compared to CT (lesion based) as reference for the detection of HCC, the sensitivity of PET/CT was 85.4%, specificity 50%, PPV 91.1%, NPV 36.4%, and accuracy 80.4%.

PET/CT revealed that the SUV max cutoff point for diagnosis of HCC was > 3, AUC 0.966, sensitivity 92.5%, specificity 75%, PPV 97.4%, NPV 50%, and accuracy 90.9% with a *P* value 0.002 (Table 1, Fig. 1A).

As regards the staging of HCC on Triphasic CT: 6 patients were diagnosed as stage 0 (15%), 15 patients as stage A (37.5%), 12 patients as stage B (30%), and 7 patients were diagnosed as stage C (17.5%). However, as regards the staging of HCC on PET/CT: 6 patients were

Table 1 (A) SUV cutoff value predicting HCC, (B) SUV cutoff value predicting stage C (extrahepatic metastases)

AUC	95% CI	P value	Cutoff	Sensitivity	Specificity	PPV	NPV	Accuracy
A	-		-				-	
0.966	0.910-1	0.002	3	92.5%	75%	97.4%	50%	90.9%
В								
0.971	0.928-1	< 0.001	5.75	92.9%	92.3%	86.7%	96%	92.5%

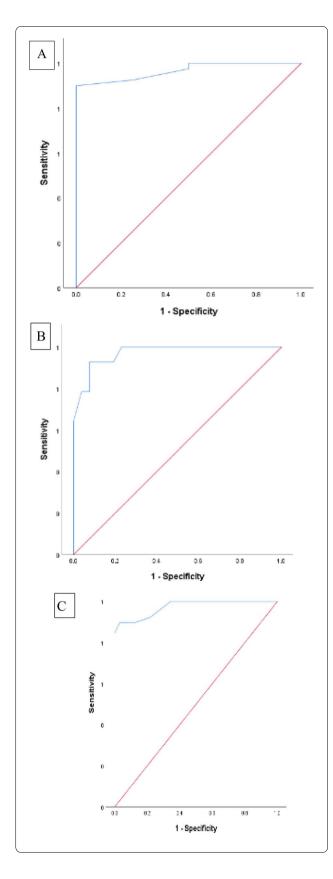


Fig. 1 A ROC curve OF PET/CT revealed its sensitivity, specificity, and the SUV max cutoff point for diagnosis of HCC, **B** ROC curve of 18F FDG PET/CT revealed sensitivity, specificity, and an SUV max cutoff point of > 5.57 for predicting that HCC has extrahepatic metastases and predicting stage C, **C** ROC curve of 18F FDG PET/CT revealed sensitivity and specificity with an SUV max cutoff point of > 3.35 for differentiating between metastatic and nonmetastatic lesions

diagnosed as stage 0 (15%), 11 patients as stage A (27.5%), 9 patients as stage B (22.5%), and 14 patients were diagnosed as stage C (35%) (Table 2).

PET/CT revealed an SUV max cutoff point of>5.57 for predicting that HCC has extrahepatic metastases and predicting stage C, AUC 0.971, sensitivity 92.9%, specificity 92.3%, PPV86.7%, NPV96%, and accuracy 92.5% with a P-value 0.001 (Table 1, Fig. 1B).

Comparison between PET/CT and triphasic CT regarding metastases showed that the number of positive metastases was 41 (57.7%) and 26 (36.6%) and several negative metastases were 30 (42.3%) and 45 (63.4%) regarding PET/CT and triphasic CT, respectively. However, the reference Metastases revealed that positive metastases were 39 (54.9%) and the number of negative metastases was 32 (45.1%.). Subsequently, comparison of the results of PET/CT and triphasic CT results to final diagnosis revealed that PET/CT diagnosed 41 lesions as metastatic lesions and 30 lesions as nonmetastatic lesions, yet there were 5 false-positive and 3 false-negative lesions. While triphasic CT diagnosed 26 lesions as metastatic lesions and 45 lesions as nonmetastatic lesions, there were 6 false-positive and 19 false-negative lesions (Figs. 2, 3, 4, 5).

In our study PET/CT showed greater sensitivity (92.3%), specificity (84.4%), PPV 87.8%, NPV 90% and accuracy (88.7%) than triphasic CT (51.3%), (81/3%), (76.9%), (57.8%), and (64.8%), respectively (Tables 3, 4).

PET/CT revealed a SUV max cutoff point of > 3.35 for differentiating between metastatic and nonmetastatic lesions with AUC 0.973, sensitivity 89.7%, specificity 87.5%, PPV 89.5%, NPV 87.5%, and accuracy 88.7% with a P-value 0.001 (Fig. 1C).

Discussion

Even though HCC is can be analyzed by the characteristics of "arterial stage hyperenhancement" and "washout" on CT or MRI, there are still confinements within the science of HCC that CT or MRI cannot reveal but that can be displayed by the metabolic data from 18F FDG PET-CT. None of these examinations can show the local disease extent or detect other metastases within the same examination. 18F FDG PET-CT, moreover, improves the location capacity for synchronous neoplasms in patients with HCC, which may be misdiagnosed as essential

Table 2 18F FDG PET/CT versus triphasic CT regarding BCLC Staging of HCCs

	Frequency	Percent
Triphasic CT		
0	6	15.0
Α	15	37.5
В	12	30.0
C	7	17.5
Total	40	100.0
18F FDG PET/CT		
0	6	15.0
Α	11	27.5
В	9	22.5
C	14	35.0
Total	40	100.0

injuries or metastasis.18F FDG PET gives hepatologists complementary imaging for local disease extent and extrahepatic metastases [3].

PET/CT may be a useful modality using an 18F-FDG tracer to recognize any collection of cancers. Malignancy usually displays high metabolism, in this way PET/CT can distinguish metabolic variations that happened before structural and anatomical changes identified by CT [4].

In any case, there are few reports comparing 18F-FDG PET/CT with conventional modalities. Early detection of extrahepatic metastasis can affect the treatment plan and affect the survival rate of patients [5]. In our study, we assessed the diagnostic role of 18F-FDG PET/CT by comparing it to triphasic CT in the detection of extrahepatic metastases and proper staging of HCC. So, we can help clinicians to choose the best imaging and establish a proper treatment plan.

Our study included 40 patients with 56 lesions diagnosed as HCC. As regards the staging of HCC on triphasic CT: 6 patients were diagnosed as stage 0 (15%), 15 patients as stage A (37.5%), 12 patients as stage B (30%), and 7 patients were diagnosed as stage C (17.5%). However, as regards the staging of HCC on 18F FDG PET/ CT it helped us to modify the final Barcelona Clinic Liver Cancer [BCLC] staging of HCC by detection of more metastases as the following: 6 patients were diagnosed as stage 0 (15%), 11 patients as stage A (27.5%), 9 patients as stage B (22.5%), and 14 patients were diagnosed as stage C (35%). Our results are concordance with Cho et al., 2014 4 which revealed a shift in seven patients' final staging using Barcelona Clinic Liver Cancer staging. This study revealed no change on BCLC stage 0 as our study, yet it also showed no change in stage C which was against our study. However, it revealed a change in the staging of early (stage A) or intermediate (stage B) HCC, which was concordant to our study. A study by Abdel Halim et al. [5] revealed that FDG-PET led to an upstaging in seven (3.7%) patients who were classified as BCLC stage (A) or (B), but none of the patients in the other stages.

18F FDG PET/CT revealed an SUV max cutoff point of > 5.57 for predicting that HCC has extrahepatic metastases and predicting stage C, with AUC 0.971, sensitivity 92.9%, specificity 92.3%, PPV 86.7%, NPV96%, and accuracy of 92.5%. However, SUV max cutoff point detected by Lee et al. [1] for predicting extrahepatic metastases was lesser than our study and measured about 3.4. On the other hand, a study done by Bains et al. [6] showed a comparable result for the prediction of metastatic disease of HCC using a cutoff value of>6 showed metastases in 88% of patients. PET/CT revealed a SUV max cutoff point of>3.35 for differentiating between metastatic and nonmetastatic lesions in patients with HCC with AUC 0.973, sensitivity 89.7%, specificity 87.5%, PPV 89.5%, NPV 87.5%, and accuracy 88.7%. However, a study done by Sarma et al. [7] showed detailed cutoff values for each of metastatic types of lesions as the following: SUV max of 5.56 pulmonary nodules, 5.35 for bony metastases, 5.74 for adrenal lesions, and from 1.8 to 9.5 for nodal disease.

In our study the comparison between 18F FDG PET/ CT and triphasic CT regarding metastases revealed that PET/CT had a greater sensitivity (92.3%), specificity (84.4%), PPV 87.8%, NPV 90% and accuracy (88.7%) than triphasic CT (51.3%), (81/3%), (76.9%), (57.8%), and (64.8%), respectively. To our knowledge, few studies compare both studies. A study was done by Hetta and Attia [8] comparing PET/CT to triphasic CT in early followup of HCC after arterial chemoembolization reported that PET/CT had a higher sensitivity and accuracy than triphasic CT but lesser accuracy. A study done by Kawaoka et al. [9] compared PET-CT, multidetector CT, in the detection of extrahepatic metastases. The results revealed a higher specificity of PET/CT for diagnosing metastatic disease in bone, lymph nodes, and lung, yet a lesser sensitivity than MDCT. Lin et al. [10] revealed a lesser sensitivity of 76.6% but a higher specificity of 98% than our results. Seo et al. [11] showed a comparable sensitivity in the detection of bony metastases about 96.7% with SUV more than 5. Another comparable result was detected on a study done by Ho et al. [12] which revealed that dualtracer PET/CT had a PPV of 97%, NPV of 90%, a sensitivity of 98%, a specificity of 86%, and an accuracy of 96% in the detection of HCC metastasis. In a meta-analysis of multiple 18F-FDG PET studies, the detected sensitivity for extrahepatic metastases diagnosis was lesser than our study (77%) yet a higher specificity was reported about 98%, respectively [5].

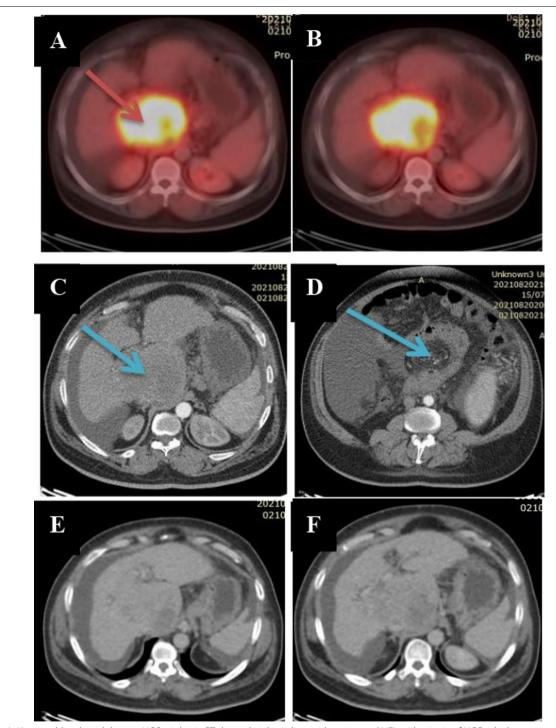


Fig. 2 A 62-year-old male with known HCC, triphasic CT showed cirrhotic liver with ascites and HFL with criteria of HCC, which was proved also by PET/CT. **A, B, G** 18F FDG PET/CT images showing a metabolically active lesion at caudate lobe (red arrow) measuring about 11 × 10 cm, achieving SUV max of 13.92. **C–F** triphasic CT showing the lesion with early arterial heterogenous enhancement with areas of break down and cystic degeneration



Our data showed that an 18F FDG PET/CT scan is better than triphasic CT in the diagnosis and staging of HCC. Nevertheless, the high cost of the investigation limits its universal use in HCC patients, making cost-effectiveness the main issue in the implementation of 18F FDG PET/CT in the standard care of the patient.

There were several limitations in our study such as the limited no of patients and the high cost of 18F FDG PET/CT. Additionally, some patients were excluded because their bad general condition cannot tolerate the infusion of contrast media, as there are many contraindications to the infusion of contrast agents due to its many adverse effects [13]. Furthermore, we did not classify patients according to the type of metastases (such as either bony or lymph nodes, etc.) Additionally, we did not classify HCC according to its type (differentiated or undifferentiated) and its effect on metastatic disease. Moreover, we did not study their different roles in the early detection of recurrent HCC after locoregional interventional treatment. Studying a higher number of patients is recommended in further study

for statistical proving that 18F FDG PET/CT has higher sensitivity than triphasic CT in diagnosis and staging of HCC.

18F FDG PET/CT is recommended for the initial staging of patients with HCC, as it more accurately delineates disease extent. We recommend further study the role of PET/CT in long-term follow-up for early detection and treatment of recurrent HCC.

Conclusions

PET/CT combines the advantages of the excellent functional information provided by PET and contrast resolution of CT, 18F FDG PET increases the rate of detection of extrahepatic metastatic lesions that improve tumor staging and modify treatment strategies. Using the standard uptake value (SUV) proved to be efficient in HCC diagnosis and staging being more related to the functional activity of the tumor cells which found hepatic, and extrahepatic.18F FDG PET/CT is more sensitive than triphasic CT in diagnosis and staging of HCC, and thus, it is important, especially in HCC staging.

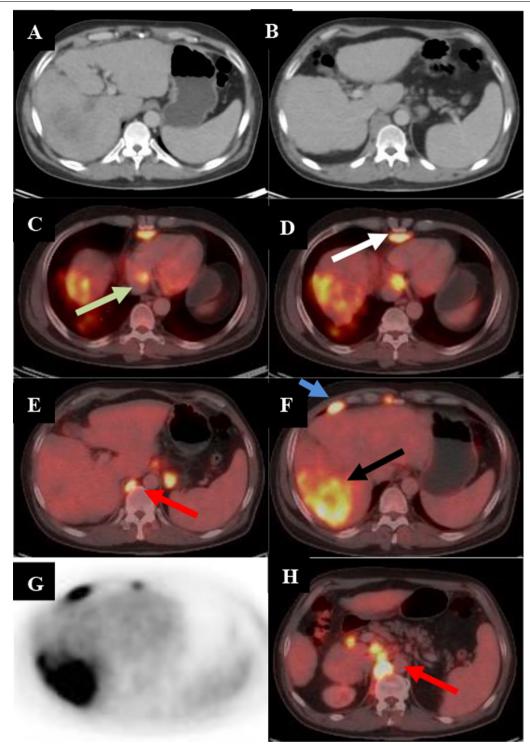
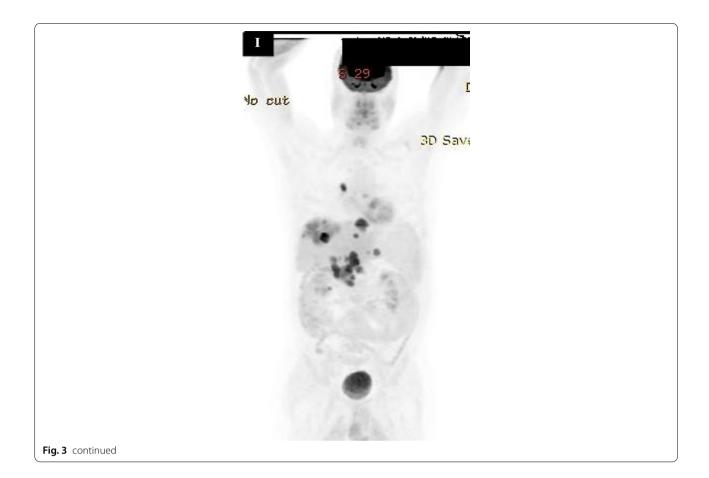


Fig. 3 A 54-year-old male patient, a known case of HCC, US was done showed HFL. **A, B** Triphasic CT showed HFL with radiological criteria of HCC, retroperitoneal deposit, and multiple suspicious LNs. **C–I** 18F FDG PET/CT showed furthermore metastases. PET/CT showing right lobe metabolically active lesion (black arrow) measuring 9 × 8 cm, with SUV max of 8.47, retrocrural LN (blue arrow) measuring 2 cm with SUV max of 12.4. Retro peritoneal deposit (red arrow) measuring 1.5 cm with SUV max of 4.72. Right hilar LN measuring 7 mm with SUV max of 8.64. Inferior pericardial focal lesion (white arrow) measuring 1.5 cm with SUV max of 5.46., **I** coronal view showing metabolically active hepatic lesion with multiple metastases



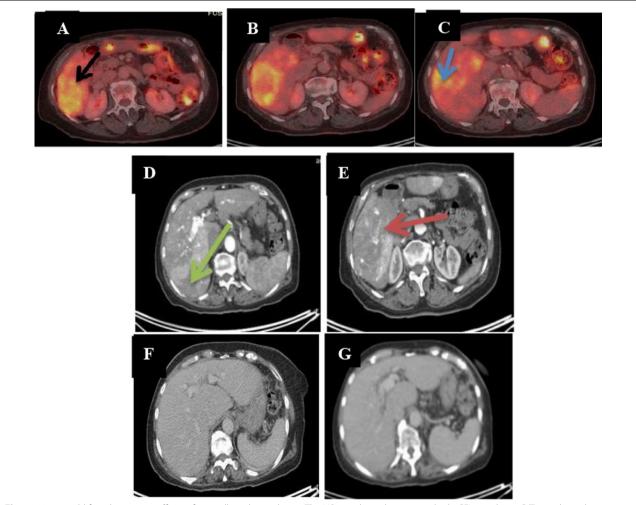


Fig. 4 69 years old female patient suffering from yellow skin and eyes. The US was done showing multiple CFLs. triphasic C/T was done showing multiple HFLs with criteria of HCC, PET/CT was done showing two right lobar metabolically active lesions, no distant metastases. **A, B, C, H, I** 18F FDG PET/CT images showing the First metabolically active lesion at segment VIII (blue arrow) measuring about 3 × 4 cm, achieving SUV max of 5.11, another Second metabolically active lesion at segment VI (black arrow) measuring about 8 × 10 cm, achieving SUV max of 5.71, and a coronal view showing multiple metabolically active HFLs. **D, E** This lesion in triphasic CT (red arrow) shows early arterial heterogeneous enhancement. **F, G** the lesion showed rapid washout in Porto venous and delayed images

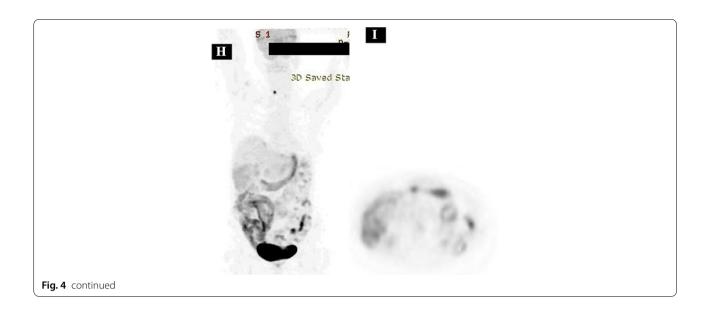


 Table 3
 Diagnostic performance of CT and 18F FDG PET/CT (according to number of metastases)

Mets	TP	TN	FP	FN	Sensitivity	Specificity	PPV	NPV	Accuracy
18F FDG PET	36	27	5	3	92.3%	84.4%	87.8%	90%	88.7%
Triphasic CT	20	26	6	19	51.3%	81.3%	76.9%	57.8%	64.8%

 Table 4 Comparison of CT and 18F FDG PET/CT (according to number of metastases)

Mets	Lung	LN	Bone	Others	Metastatic lesions	Non metastatic lesions
18F FDG PET	21 (29.6%)	32 (45.1%)	16 (22.5%)	2 (2.8%)	41 (57.7%)	30 (42.3%)
Triphasic CT	19 (26.7%)	26 (36.6%)	18 (25.4%)	8 (11.3%)	26 (36.6%)	45 (63.4%)

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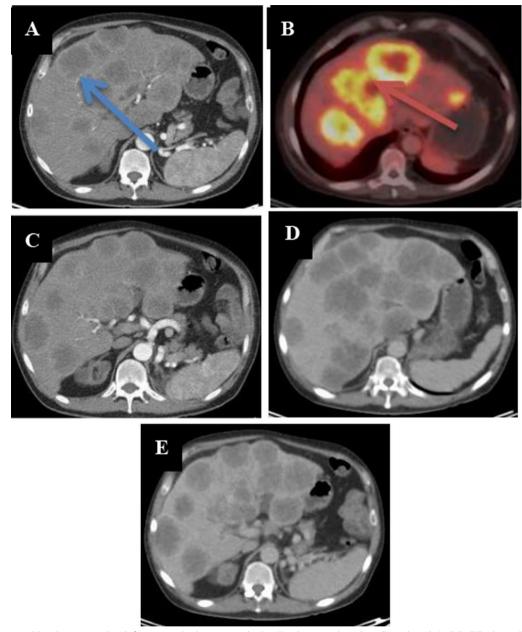


Fig. 5 A 55-year-old male presented with fever 4 weeks duration, multiple HFLs discovered incidentally in the US. **A, C, D, E** Triphasic CT revealed multiple HFLs, these lesions show peripheral arterial enhancement (blue arrow), **D, E** with washout in delayed images. **B** 18F FDG PET/CT revealed multiple metabolically active hepatic focal lesions replacing the whole hepatic parenchyma, the largest one (red arrow) measuring about 5 × 4 cm, achieving an SUV max of 8.15

Abbreviations

18F-FDG: 18F-fludeoxyglucose; AFP: Alpha-fetoprotein; AUC: Area under the curve; BCLC: Barcelona clinic liver cancer; CA: Contrast agent; CT: Computed tomography; HCC: Hepatocellular carcinoma; HFL: Hepatic focal lesion; MRI: Magnetic resonance imaging; NPV: Negative predictive value; PET: Positron emission tomography; PPV: Positive predictive value; ROC: Receiver operating characteristic curve; SUV: Standardized uptake value; US: Ultrasound.

Acknowledgements

Not applicable.

Author contributions

MB: Suggested and developed the research idea, shared in data collection and analysis, shared in statistical analysis, shared in manuscript writing, revision and editing, Prepared MRI cases, performed the required measurements, and prepared figures and tables. YA, EB, ZA, AS: shared in data collection and analysis, shared in reviewing the literature, shared in performing statistical analysis, shared in manuscript writing, and shared in preparing MRI cases. All authors read and approved the final manuscript.

Funding

No Funds, sponsorship, or financial support to be disclosed.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

This study had approval by the Research Ethics Committee of the Faculty of Medicine at Ain shams University in Egypt on October 2020; Reference Number of approval: FMASU M S 539/2020., FWA 000017585. All participants included in this study gave written informed consent in this research. If any patient was unconscious at the study time, written consent for their participation was given by their own legal guardian.

Consent for publication

All participants included in this research gave written informed consent to publish all the data contained within this study. If the patient was unconscious when consent for publication was requested, written informed consent for the publication of all this data was given by their own legal guardian.

Competing interests

The authors declare that they have no conflicts of interest.

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Received: 29 March 2022 Accepted: 3 June 2022 Published online: 17 June 2022

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