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Original Article, PET/CT.

Prediction of Prognosis in Malignant Pleural Mesothelioma using ^{18F} Fluoro-deoxy-glucose PET/CT Metabolic Parameters.

ElKholy E.[1] Koura R.[1] Moustafa H.[2] Maksoud A.[1]

[1]Nuclear Medicine, National Cancer Institute (NCI), [2]Department of Clinical Oncology and Nuclear Medicine, Faculty of Medicine, Cairo University, Egypt.

ABSTRACT:

Background: Malignant pleural mesothelioma (MPM) is known to have poor prognosis and low survival rate. Prognostic information provided by ^{18F} fluoro-deoxy-glucose (FDG) PET/CT metabolic parameters in initial staging of MPM patients was the aim of this study. **Materials & Methods:** All 18F-FDG PET/ CT scans used for pretreatment staging of MPM (n =56) were reviewed. Overall survival (OS) was correlated with standardized uptake values (SUV) including mean, maximum and peak values, metabolic tumor volume (MTV) and total lesion glycolysis (TLG)for primary and primary/liver ratio as well as demographic, clinical characteristics and pathological data. **Results**: Overall survival rate at 1 year was 70.1. ROC curve analysis of 18F-PET/CT for primary site; SUVmax (p=0.030), SUVpeak (p=0.023), SUVmean (p=0.019), TLG (p =0.010) and only TLG (p =0.038) of primary/liver ratio were significantly associated with prediction of disease progression. The other parameters were of borderline significance. By univariate OS analysis in relation to 18F-PET/CT for primary site; SUVmean (P=0.002) SUVpeak (P=0.026) TLG (P=0.006) and for primary/liver ratio; SUVmax (P=0.004), SUVpeak (P=0.005), SUV mean (P= 0.017) and TLG (P=0.016) were significantly associated with OS. Regarding multivariate analysis including the 3 significant variables on univariate level, only SUVmean (P=0.005) for primary site & SUVmax (P= 0.007) for PET/CT of primary site/ liver ratio, were independently predicting OS at the final step of the model.

Conclusions: Functional 18F-FDG PET/CT volume based metabolic parameters indices for primary and primary to liver ratio are non-invasive, low cost and time effective method to provide prognostic information for malignant pleural mesothelioma.

Keywords: PMP, Semi-quantitive, FDG

Corresponding author: Esraa Elkholy **E-mail: esso.kholio@gmail.com**

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INTRODUCTION:

Malignant pleural mesothelioma (MPM) is a rare, yet fatal tumor, whose incidence is increasing worldwide. (1,2,3). Prognosis with MPM is poor and median survival ranges from 8 to 14 months from diagnosis (2). PET/CT shown to have a role in the detection of extra-thoracic metastasis; however, recent studies have demonstrated using this imaging modality in all phases of the MPM diagnosis and treatment. [(4)]. The aim of this study is to assess the prognostic value of the ^{18F} fluoro-deoxy-glucose (FDG) PET/CT metabolic parameters in initial staging of MPM patients.

PATIENTS AND METHODS:

Population of study & disease condition:

This retrospective study enrolled 56 adult patients with proven MPM by pathology. They were all referred to Nuclear Medicine unit in the National Cancer Institute (NCI) for initial pre-therapy assessment, between the periods of January 2016 to May 2021. Medical records provide the clinical information (sex, age, pathological data, imaging findings), response to treatment and survival data. **Study setting: Inclusion criteria:** Adult patient >18 years old, patients with pathologically proven malignant pleural mesothelioma. Referred for initial assessment – No prior chemo or radiotherapy. **Exclusion criteria:** Patients with double primary & patients with prior chemotherapy or radiotherapy.

^{18F} FDG PET/CT scanning: Patient preparation: Fasting for 5-6 hours before the study, avoid severe muscles exercise for 24 hours prior to the study. Blood glucose level before the 18F-FDG administration should not exceed 160 mg/dl. Injected dose: Approximately 0.14 mCi/kg body weight of 18-F FDG. **Image acquisition:** FDG PET/CT study was done using Discovery PET-CT scanner (GE Medical System, USA), and were processed using iterative reconstruction (3 iterations, 21 or 22 subsets) with time of-flight corrections. 18F-FDG PET/CT volume measurements were considered exploratory and not used for treatment decisions. Imaging starting 45 - 60 min following FDG injection. Initially, patients were examined in the supine position

with arms elevated, and CT scanning was started with the following parameters: 140 kV, 80 mA, PITCH: 1.375, slice thickness: 3.75 mm. The CT scans were acquired from skull vault down to the mid thighs followed by immediate PET acquisition (6-8 bed positions; acquisition time, 2 min/bed position). From the raw emission data collected, the image was reconstructed by iterative reconstruction with CT-derived attenuation correction. **Data Analysis P**ET/CT images were reviewed on the work station, which enables display of PET images, CT images and fused PET/CT images, then interpreted by 2 experienced nuclear medicine physicians. For semi-quantitative analysis, spherical volume of interest (VOI) over the regions of interest (site of primary tumor) were applied manually in order to exclude non-tumor soft tissue (e.g., heart, liver and kidney) and being compared with 18F-FDG PET images to ensure that all tumor was included. Then record the maximum standardized uptake value (SUV max), peak standardized uptake value (SUV peak), mean standardized uptake value (SUV mean), Metabolic Tumor Volume (MTV) & Total lesion glycolysis (TLG). MTV is defined as the number of voxels within the VOI, which had a greater uptake than the chosen background threshold. VOIs were adjusted using a threshold ranging from 10% to 40 % of SUVmax. Using different thresholds was more suitable regarding the variation of initial FDG uptake of the primary tumor. TLG is calculated as MTV multiplied by the mean SUV (TLG = MTV × mean SUV). Hepatic reference SUVmean & SUVmax threshold are calculated by drawing 3 cm spherical ROI in the normal right lobe hepatic dome, where its parameters are considered the reference activity, for further quantitative analysis to calculate the primary to liver ratio. **Follow up:** Follow up data including clinico-laboratory and radiological data were retrieved for all patients from their medical records to evaluate response to therapy till the last visit using the PET Response Criteria in Solid Tumors (PERCIST 1.0). **Statistical analysis:** Data management and analysis was performed using Statistical Package for Social Sciences (SPSS) vs. 25. Numerical data were checked for normality and were statistically described in terms of mean (standard deviation) or median (range) as appropriate. Categorical data were described as numbers and percentages. Survival analysis was done using Kaplan-Meier method and comparison between two or more

survival curves using log rank test with **Bonferroni** adjustment when necessary. All statistically significant factors on Kaplan-Meier analysis entered the multivariate cox-regression analysis using forward likelihood-ratio (LR) method for variable selection. Overall survival (OS) was calculated from the date of diagnosis to the date of death or last follow-up. Hazard ratios were computed for significant factors in the last step of cox-regression with 95% confidence interval estimates. A receiver operator characteristic (ROC) analysis was performed for determining best cutoff value for the 18F-FDG PET/CT Parameters to predict progression. Accuracy is measured by the area under the ROC curve (AUC). An area close to 1.0 represents a perfect test, while an area close to 0.5 represents a worthless test. Sensitivity and specificity of all cutoff values were calculated. All tests were 2 tailed and P-value < 0.05 was considered statistically significant.

RESULTS:

Descriptive Statistics:

Among the enrolled 56 adult patients. Male to female ratio is 3:1. The mean age 60.7 years (ranged from 25 to 79 years). The median follow up period for the study population was 7.07 months (0.39-35.99). Epithelioid is the main pathological feature in 55 patients (98.2%). Demographic, pathologic data and clinical characteristics in T**able (1)**. Baseline FDG PET/CT scans were retrieved, and PET volumetric images were analyzed for metabolic parameters SUVmax, SUVpeak, SUVmean, MTV and TLG for primary tumor and tumor/liver ratio. The patients showed SUV max with median 10.7 (ranged from 3.3 to 41.3) for primary tumor and with median 3.5 (ranged from 1.4 to 18.0). The other parameters were illustrated on **Table (2)**. The patient were followed for duration of 6 to 12 months by chest CT or follow up PET/CT. Twenty six patients showed disease progression, 16 with disease regression (2 of them showed complete resolution of metabolic activity), 5 patients showed stationary course, unfortunately 14 patients died and 9 patients lost follow up.

Table (1): Demographic, pathologic data and clinical characteristics of patients (n=56).

Characteristics		**n**	**(%)**
Age ***mean (SD) (25-79)***		**60.7**	**(10.2)**
Gender	***Male***	**42**	**(75.0)**
	Female	**14**	**(25.0)**
Side	***Left***	**24**	**(42.9)**
	Right	**30**	**(53.6)**
	Bilateral	**2**	**(3.6)**
Characteristics		**n**	**(%)**
Pathologic type	***Epithelioid***	**55**	**(98.2)**
	Non-epithelioid	**1**	**(1.8)**
Pattern	***Diffuse***	**29**	**(51.8)**
	Nodular	**10**	**(17.9)**
	Combined	**17**	**(30.4)**
TNM staging			
T, (n=55)	***T1***	**34**	**(61.8)**
	T2	**2**	**(3.6)**
	T3	**3**	**(5.5)**
	T4	**16**	**(29.1)**
N, (n=55)	***N0***	**13**	**(23.6)**
	N1	**27**	**(49.1)**
	N2	**15**	**(27.3)**
M	***M0***	**45**	**(80.4)**
	M1	**11**	**(19.6)**
Thickness, ***(n=46)***		**2.0**	**(0.8-4.4)**
Mass Max. diameter, ***(n=27)***		**4.0**	**(0.9-19.0)**

Table (2): Metabolic parameters in initial ^{18}F-FDG PET/CT for primary site and primary / liver ratio (n=56)

	Primary site		**Primary/liver ratio**	
^{18}F-FDG PET/CT Parameters	**Median**	**(Range)**	**Median**	**(Range)**
SUV $_{max}$	10.7	(3.3-41.3)	3.5	(1.4-180)
Peak	8.2	(2.8-33.9)	3.1	(1.3-16.1)
SUV $_{mean}$	3.7	(1.3-14.6)	1.8	(0.7-8.1)
MTV	716.7	(83.3-2017.6)	48.4	(4.4-181.7)
TLG	2245.5	(199.1-14652.9)	70.3	(6.7-13961.7)

ROC analysis for F-FDG PET/CT Parameters (n=47)

A/ Primary site PET/CT Parameters

ROC curve was used to mark a prognostic primary SUVmax (1ry SUVmax), SUVpeak, SUVmean, TLG & MTV (derived from PET/CT scans) cut off points that could predict progression with best compromise between sensitivity & specificity.

ROC curve succeeded to mark such cut-off point of 9.55 for 1ry SUVmax, SUVmean of 3.65, 7.55 for SUVpeak, 709.25 for 1ry MTV & 2625.60 for TLG, with the illustrated detailed AUC, sensitivity, specificity & 95% confidence interval**.** MTV is the only parameters shows no statistically significant. **Figures (1).** Regarding the primary to liver (P/L) parameters, Roc curve analysis succeeded to mark such cut-off point of 30.9 for P/L SUVmax, 3.07 for SUVpeak 1.57 for P/L SUVmean, 38.99 for MTV and 57.38 for TLG. **Figure (2).**

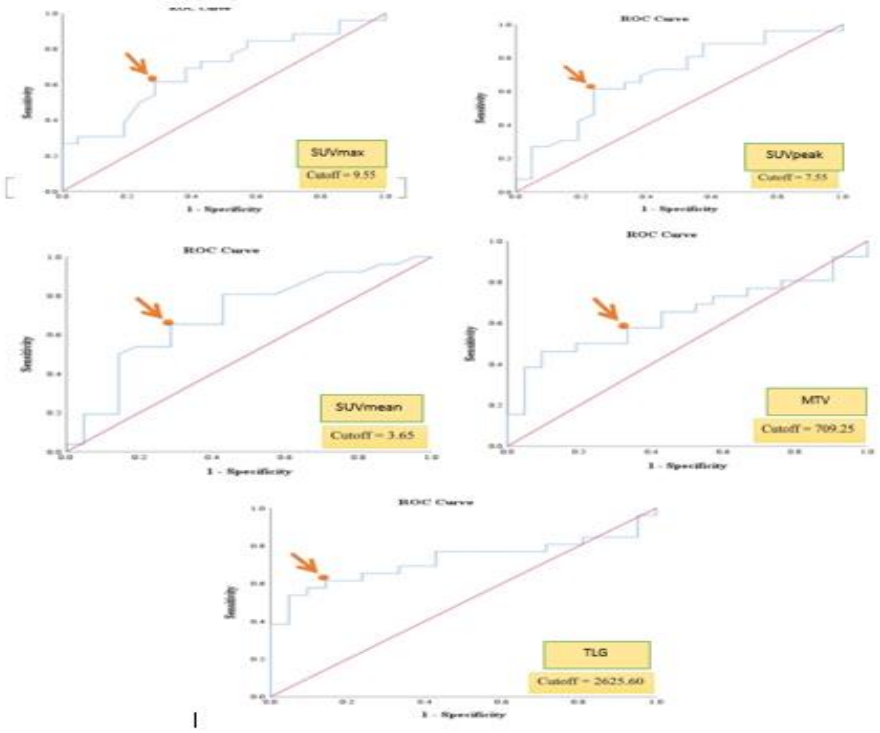

Figure (1) ROC curve analysis of initial FDG PET/CT primary volume based metabolic parameters to predict progression.

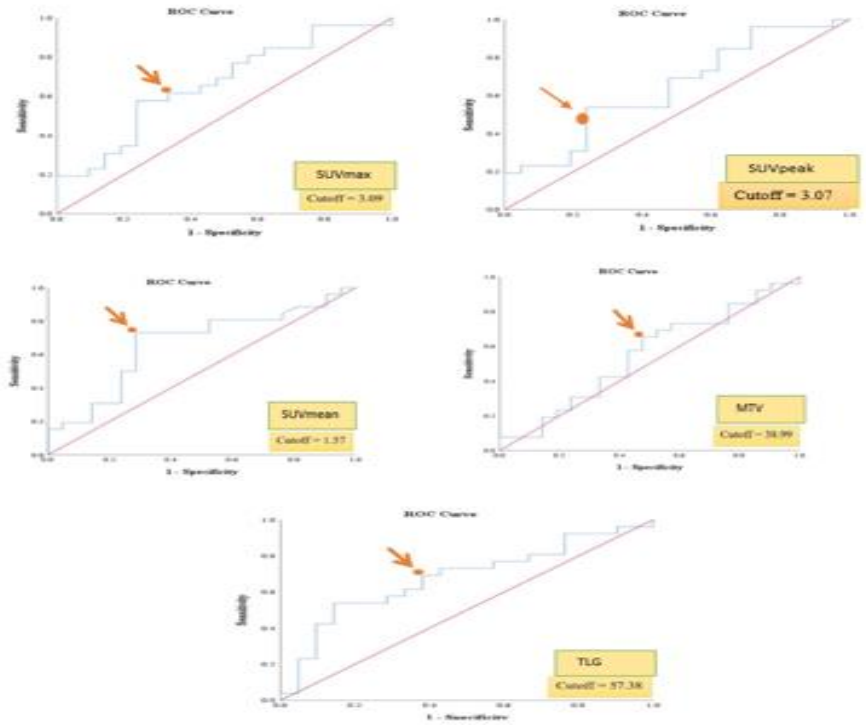

Figure (2) ROC curve analysis of the initial ^{18} F-FDG PET/CT primary/liver ratio volume based metabolic parameters to predict progression.

Overall survival (OS):

Total number of cases 47 patients, while remaining cases have missing survival dates. Number of events is 14 with censored of 27 (65.9%) **Figure (3).** Overall survival rate at 1 years is recorder to be ~ 70.1% with median 19.28 months.

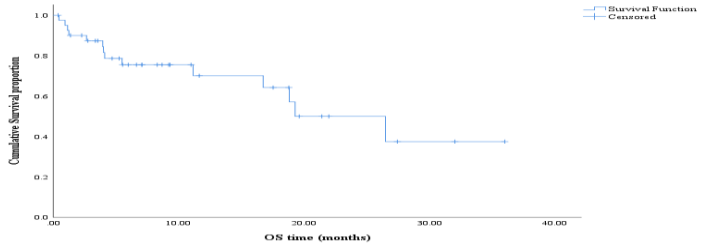

Figure (3): Overall survival (OS) for the whole group (n=41)

A/ Overall survival in relation to primary site & PET/CT Parameters:

Kaplan-Meier univariate OS analysis for 41 patients whose survival dates were available in relation to 18 F-FDG PET/CT volume based metabolic parameters for primary site. Detailed overall survival in relations to different other PET parameters are illustrated in **Table 6** , all shows statistical significance except for SUVmax & MTV. **Table (3) Figure (4)**.

Table (3): Kaplan-Meier Univariate OS analysis in relation to metabolic parameters in initial FDG PET/CT primary site (n=41)

Characteristics	Primary site				Primary/liver ratio			
SUV max	≤ 9.55	19	80.0	0.107	≤ 3.09	20	86.1	0.004 *
	> 9.55	22	62.8		> 3.09	21	54.9	
Peak	≤ 7.55	20	81.3	0.026 *	≤ 3.07	23	82.4	0.005 *
	> 7.55	21	60.6		> 3.07	18	52.7	
SUV mean	≤ 3.65	20	85.3	0.002 *	≤ 1.57	17	82.0	0.017 *
	> 3.65	21	57.0		>1.57	24	61.7	
MTV	≤ 709.25	19	69.3	0.230	≤ 38.99	14	67.5	0.495
	>709.25	22	69.4		>38.99	27	71.3	
TLG	≤ 2625.60	21	83.5	0.006	≤ 57.38	15	84.6	0.016 *
	>2625.60	19	53.4		>57.3 8	26	61.4	

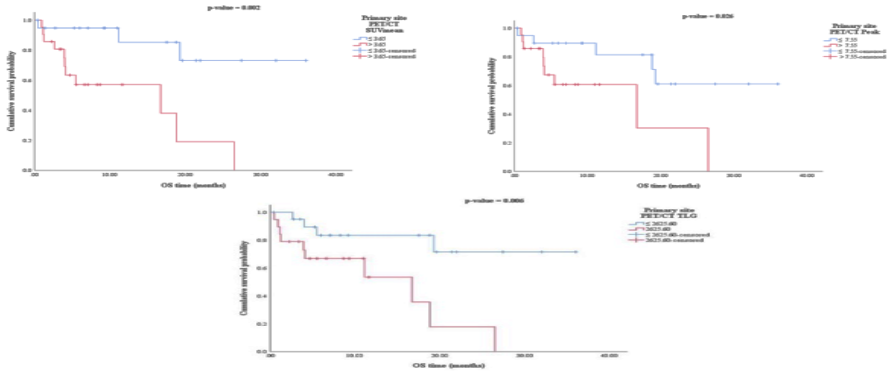

Figure (4): OS in relation to primary site PET/CT proved statistically significant, SUVmean, SUVpeak & TLG.

In Cox multivariate regression analysis for primary site succeed to set cut off value of 1.891 for SUVmean with standard error of 0.679, hazard ratio of 6.696, 95% confidence interval of (1.751-25.066) & (P=0.005). **Table (4).**

Table (4): Cox multivariate regression analysis for OS in relation to FDG PET/CT parameters for primary site and for SUVmax on primary/liver ratio (n=40)

	B	STE	p-value	HR	95 % CI for HR
SUV mean	1.891	0.679	0.005 *	6.625	(1.751 - 25.066)
SUV max	1.695	0.631	0.007 *	5.447	(1.582 - 18.754)

OS : Overall Survival, HR: Hazard Ratio, CI: Confidence Interval, STE: standard Error,
* Statistically significant at p-value < 0.05 level

B/ Overall survival in relation to primary to liver (P/L) ratio PET/CT Parameters:

Primary / liver ratio (P/L%) succeed to set optimal cut offs to (P/L) metabolic parameters for OS. 20 of patients with (P/L) SUVmax below or equal to 3.09 with 86.1% 1 year overall survival and 21 of patients with (P/L) SUVmax above 3.09 with 54.9 % 1 year overall survival which reach statistical significance (P=0.004). Only MTV could not achieve statistical significance **Figure (5)**

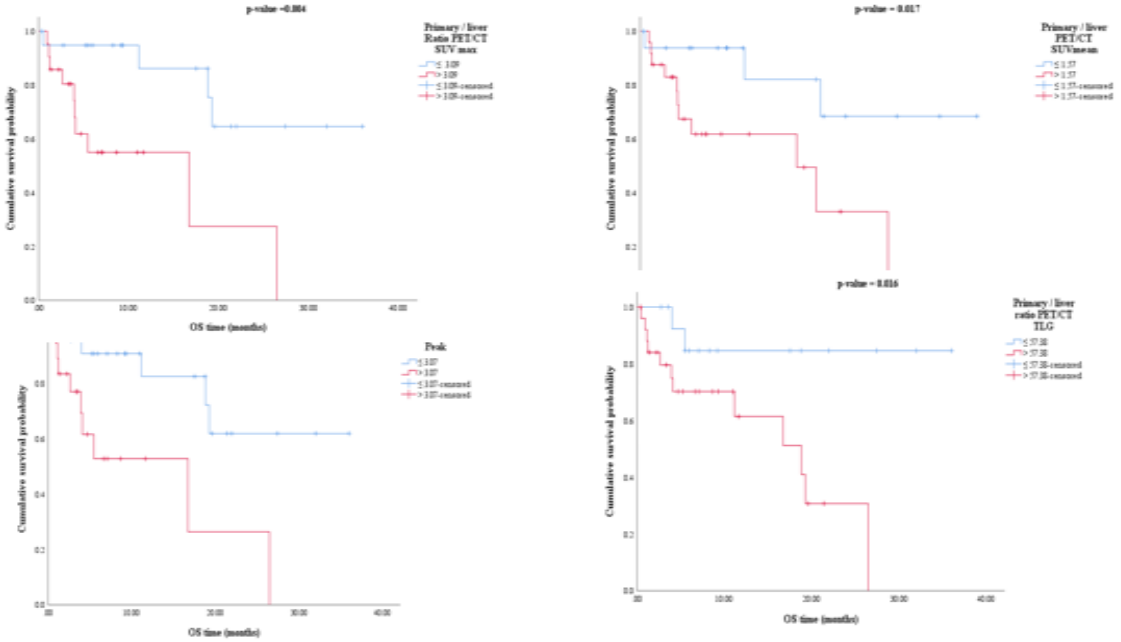

Figure (5): OS in relation primary to liver ratio PET/CT SUVmax, SUVmean, SUVpeak & TLG.

In Cox multivariate regression analysis for OS in relation to ^{18} F-FDG PET/CT volume based metabolic parameters for primary site succeed to set cut off value of 1.695 for SUVmax with standard error 0.631, hazard ratio of 5.447, 95% confidence interval of (1.582-18.754) & (P=0.007). **Survival Correlation with other prognostic factors:** Kaplan-Meier univariate OS analysis for 41 patients whose survival dates were available in relation to demographic and clinical characteristics of these patients. Age, extension and thickness of primary as well as presence of distant metastases are the parameters which statistically proved associated with poor prognosis and reduced overall survival. **Table (5) figure (6).**

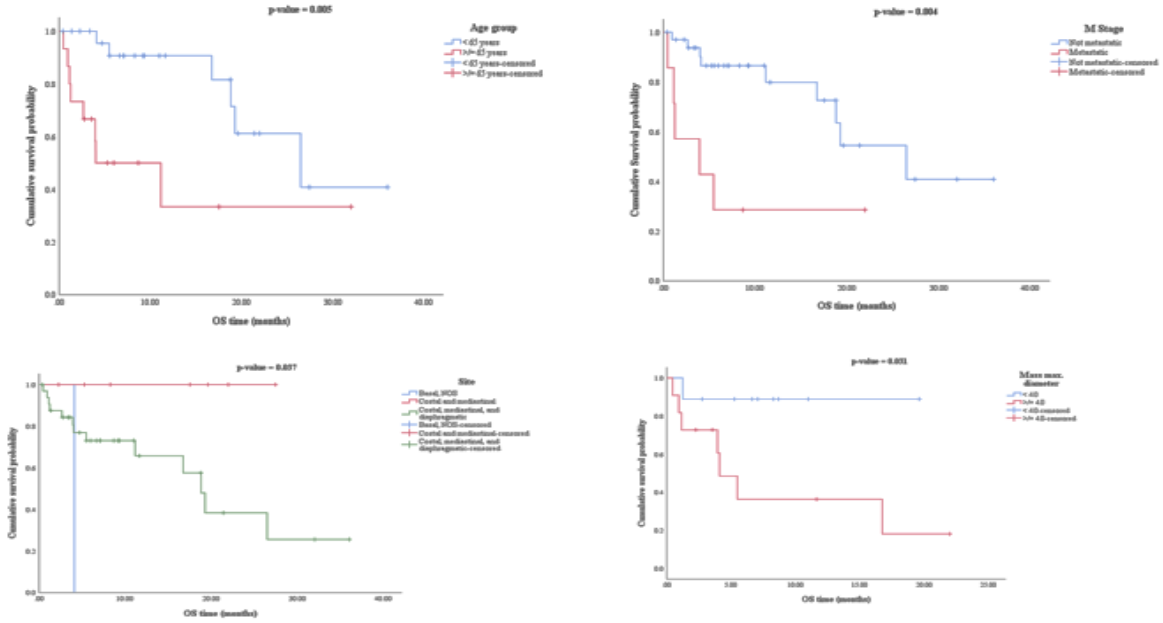

Figure (6): Overall survival (OS) in relation to age, site, M staging & maximum tumor diameter

Table (5): Kaplan-Meier univariate OS analysis in relation to demographic, clinical characteristics and pathologic data of patients (n=41)

Characteristics		n	1 Y-OS (%)	p-value
Age	*< 65 years*	26	90.7	0.005 *
	≥ 65 years	15	50.0	
Gender	*Male*	30	62.0	0.137
	Female	11	90.0	
Site **	*Costal, mediastinal, and diaphragmatic*	33	65.8	0.037 *
	Costal and mediastinal	7	100.0	
Side	*Left*	15	78.0	0.756
	Right	25	64.1	100.0
	Bilateral	1	100.0	
Pathologic type	*Epithelioid*	40	69.4	0.593
	Non-epithelioid	1	100.0	
Pattern	*Diffuse*	21	80.2	0.181
	Nodular	8	38.9	
	Combined	12	75.0	
TNM staging				
***T**, (n=40)*	*T1 and T2*	26	78.5	0.122
	T3 and T4	14	50.5	
***N**, (n=40)*	*N0*	11	69.3	0.661
	N1	20	76.5	
	N2	9	57.1	
M	*M0*	34	79.9	0.004 *
	M1	7	28.6	
Thickness	*< 2.0*	12	73.3	0.348
	≥ 2.0	21	78.2	
Mass Max. diameter	*< 4.0*	9	88.9	0.031 *
	≥ 4.0	11	36.4	

* Statistically significant at p-value < 0.05 level

Cox multivariate regression analysis for OS succeeded to mark such cut-off point of 3.011 with age group with sensitivity 1.233%, (p-value 0.015), Hazard ratio of 20.316 & 95% confidence interval of (1.814-227.589), cut-off point of 2.851 with largest nodule maximum diameter with sensitivity 1.278%, (p-value 0.026), Hazard ratio of 17.298 & 95% confidence interval of (1.414 -211.629), **Table (6) Figure (7)**.

Table (6) Cox multivariate regression analysis for OS in relation to demographic, clinical and pathologic data (n=20)

	B	STE	p-value	HR	95 % CI for HR
Age group	3.011	1.233	0.015 *	20.316	(1.814 - 227.598)
Max. diameter	2.851	1.278	0.026*	17.298	(1.414 - 211.629)

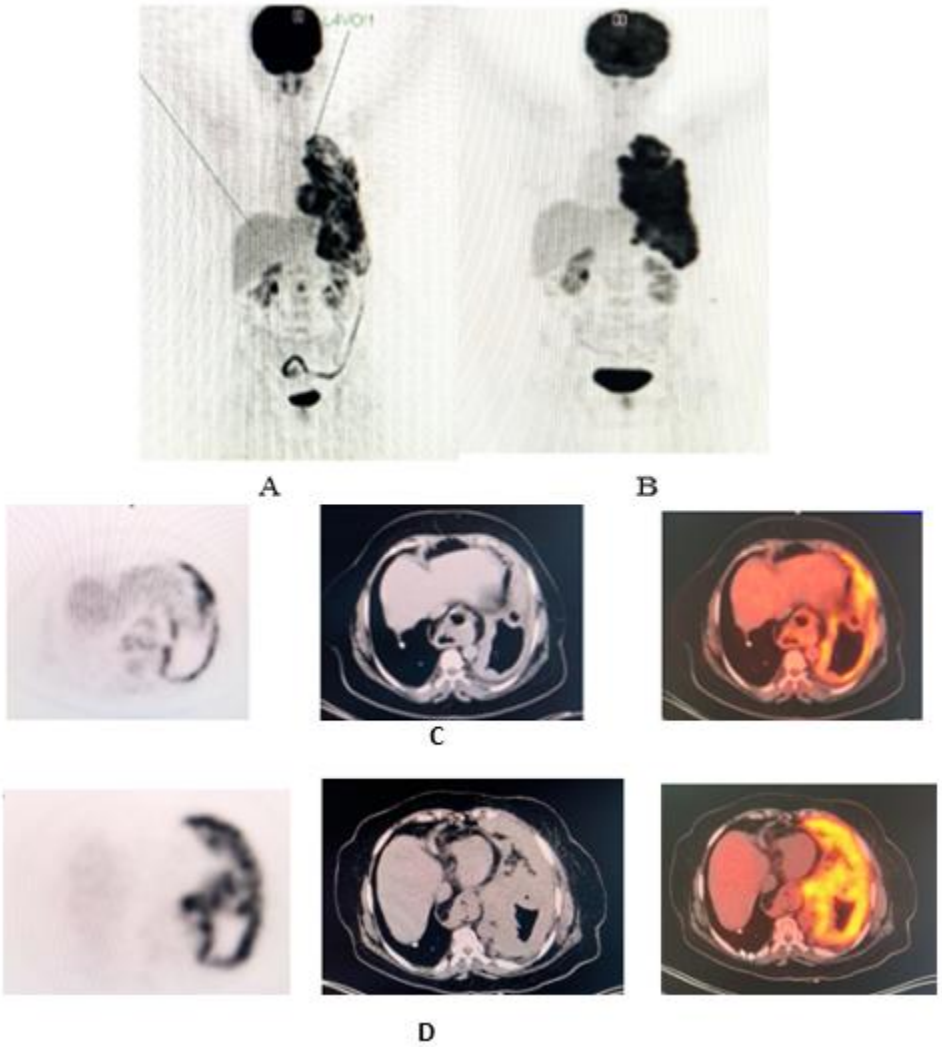

Figure (7): ^{18F} FDG PET/CT whole-body maximum intensity projection image in initial stage (A) and axial initial [18F] FDG (PET, CT & fused PET/CT images) images (C) showing hyper-metabolic primary left pleural malignant mesothelioma, with Initial parameters SUVmax ~15.8 SUVmean~ 5.5 SUVpeak~12.8 MTV~1109 & TLG~6098.3. B & D = Follow up [18F] FDG PET/CT whole-body maximum intensity projection image (b) and axial [18F] (PET, CT & fused PET/CT images) showing evident disease progression.

DISCUSSION:

Patients with malignant pleural mesothelioma known to have a poor prognosis. Prognostic information is therefore potentially valuable in managing patients. The aim of this study was to evaluate the potential of initial 18F-FDG PET/CT to predict prognosis and survival parameters in patients with malignant pleural mesothelioma (MPM). Our results showed that 18F-FDG PET/CT volume based metabolic parameters indices are non-invasive, low cost and time effective method that could predict prognosis on malignant pleural mesothelioma. Initial primary tumor SUVmean, SUVpeak and TLG were significantly correlated with overall survival with (P=0.002), (P=0.026) and (P=0.006) respectively, however the multivariate analysis including the 3 significant variables; (SUVmean, Peak and TLG) only SUVmean (P= 0.005), was independently predicting OS at the final step of the model. Figure [7] The determination of initial primary to liver ratio metabolic parameters in current study added SUVmax to the other parameters with (P= 0.004) (P=0.005), (P= 0.017) and (P= 0.016) respectively, which was independently predicting OS, by multivariate analysis. In review of previous studies, cut-off values differed from one study to another according to the enrolled populations, with no well-established cut-off value recommendations A similar study done by **Klabatsa** et al. on 60 patients revealed by uni-variable analysis that TLG (p =0.024) and MTV (p =0.038) proved significantly associated with overall survival, while multivariable analysis elicit that TLG was relatively associated with OS but at borderline statistical significance (p =0.058). [6] Another study by **Lee** et al. enrolled much smaller number of 13 patients, most of them 8 (62%) developed recurrence or tumor progression. Analysis of ROC curve, showed significant differences for MTV (P = 0.045). Multivariate analysis showed that MTV were independent factor associated with tumor progression. [7] A retrospective study made by **Doi** et al. reviewed the data of 188 patients, univariate analyses, showed shorter survival associated with high SUVmax, MTV and TLG. High TLG value was significant independent predictor of poor survival outcomes. [8] In contrary to our study, **Zucali** et al. study revealed that baseline SUVmax & TLG parameters showed a statistical significance with OS (P<0.05) [9]. Similar result was explored by **Bille** et al. on study carried on 191 patients

using SUVmax (≤8.1 versus >8.1), showed (p = 0.037) were associated with OS on uni variant analysis. The level of SUVmax was variable and not fixed in different studies, on our work ROC curve recorded 9.55 as best cutoff value related to overall survival[10]. A study by **Lim** et al. on 54 study patients correlate the SUVmax with pathologic subtype. The median SUVmax was 9.9. (was 5.5 in epithelioid subtype, 11.7 in those with sarcomatoid/biphasic subtype and 13.3 in NOS subtype (P = 0.003). 10.1 was optimal cutoff values of SUVmax to predict mortality. In multivariate analysis, SUVmax was significantly associated with overall survival in all patients (P = 0.003) and in patients with epithelioid subtype (P = 0.012), but not in those with non-epithelioid subtype. [11] Also, **Hall DO** et al. illustrated that 65 patient had PET/CT, where baseline measurements of SUVmax FDG PET/CT (P=0.005), MTV (P=0.0009) and TLG (P=0.002) were significantly related to OS. [12]. In retrospective study by **Koyuncu** et al. included 60 patients. In univariate analysis, SUVmax higher than 8 (P=0.023) was negative prognostic factors[13]. Another retrospective study by **Lococo** et al. included 141 patients. A univariate analysis, with SUVmax proved to be independently associated with overall survival [14]. Terada et al. stated that there was difference in overall survival between the two subdivided groups with SUVmax levels less and more than 3.5 (p=0.02) [15]. Finally, in retrospective analysis done by **Abakay** et al. enrolled on 177 patients, significant poor prognostic factors were proved with level of SUVmax > 5 (p < 0.05). In multivariate analysis, level of SUVmax > 5 increased poor prognosis 4.34 time[16]. On current study, univariate analysis in relation to demographic, pathologic and clinical characteristics of patients showed that; Age (P= 0.005), site (P= 0.037), M stage (P= 0.004) and Mass max. Diameter (P= 0.031) were significantly associated with OS. In **Doi** et, al study, non-epithelioid histologic type, high T stage, and high TNM stage were associated with shorter survival in univariate analyses, yet multi-variant analysis showed that non-epithelioid histologic type and TLG are significant independent predictors of poor survival outcomes. [17]. In contrary to **Doi** et, al study showed no statistical significance differences were found for any PET parameters the pathology. The limitation of the current study include: first, relatively small number of the studied cohort with inadequate representation of all pathological subtypes. Second, small number of patients

with regressive course of disease limited the statistical confidence for positive and negative predictive values. Third, variation in therapy protocols and duration of disease as well as follow up period. Forth, one of the main limitations was the lack of certain validation model to ensure the above-mentioned model accuracy especially in measurement of MTV. Finally, a possible bias in this study is the biopsy taken prior to PET examination that may influence the actual FDG activity of the primary tumor. However, we can consider our data to contribute significant information that might aid in the development of MPM prognostic information. So, we recommend, follow up prospective study to validate the accuracy and specificity of the created model especially for the measurement of constant threshold to reach optimum MTV evaluation.

CONCLUSIONS:

We can conclude that 18F-FDG PET/CT volume based metabolic parameters indices are non-invasive, low cost and time effective method, to provide prognostic information for malignant pleural mesothelioma patients. Initial primary tumor (SUVmean, SUVpeak & TLG) as well as primary tumor/ liver ratio parameters (SUVmax, SUVmean, SUVpeak & TLG) were significantly correlated with overall survival. Age, site of tumor, M stage and mass maximum diameter are significantly correlated with Overall survival.

Declarations Ethics approval: The study is approved by National Cancer Institute Cairo University ethical and scientific committee.

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