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The Role of 18-FDG PET/CT Metabolic Parameters in Predicting Prognosis in Advanced Intrahepatic Cholangiocarcinoma

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Abstract

Objective: Intrahepatic cholangiocarcinoma is the second most frequently encountered primary tumor of the liver after hepatocellular carcinoma. In patients who do not have surgical or other local treatment options, systemic chemotherapy is the standard treatment. However, prognostic factors are not clear for patients with advanced disease who do not have the ability to undergo a surgical operation. In many tumors, there are studies demonstrating the pretreatment effect of positron emission tomography with fluorodeoxyglucose (FDG-PET) metabolic parameters on prognosis. However, there are a small number of studies that research the effect of FDG-PET metabolic parameters on the prognosis in advanced intrahepatic cholangiocarcinoma. We aimed to investigate the relationship between FDG-PET metabolic parameters and survival in advanced intrahepatic cholangiocarcinoma.

Methods: The medical records of 50 advanced intrahepatic cholangiocarcinoma patients from Istanbul Bilim University Medical Oncology Clinic between 2012 and 2018 were reviewed retrospectively. The relationship between patient survival, demographic characteristics and FDG-PET metabolic parameters (SUVmax, metabolic tumor volume, and total lesion glycolysis) was analyzed.

Results: Each unit of increase in metabolic tumor volume increases the risk of death by 1.0057 times, and each unit of increase in total lesion glycolysis increases the risk of death by 1.0034 times. The Cox regression model was found to be significant for metabolic tumor volume and total lesion glycolysis values but not for SUVmax values.

Conclusion: FDG-PET metabolic parameters, such as metabolic tumor volume and total lesion glycolysis, contribute to the prognosis, and routine measurement of these parameters will be beneficial.

Keywords: Cholangiocarcinoma; FDG-PET; Prognosis; Prediction; Metabolic parameters

Introduction

ICC is the second most frequently encountered primary tumor of the liver after hepatocellular carcinoma. ICC originates from the epithelium of intrahepatic bile ducts. Although ICC is a rare tumor, its incidence is increasing worldwide [1].

FDG-PET/CT imaging of cancer is the combined techniques of positron emission tomography with fluorodeoxyglucose (FDG-PET) and X-ray computerized tomography (CT) scanners and has become a standard component of diagnosis and staging in oncology [2]. The role of FDG-PET/CT in the staging of cholangiocarcinoma is not clear. Although it does not provide additional information to magnetic resonance imaging (MRI) and CT in imaging primary tumors, it has been shown that preoperative FDG-PET/CT exhibits occult distant metastases better, changing the treatment approach in approximately 1/4 of patients [3-10]. Therefore, FDG-PET/CT imaging before surgery in operable ICC is recommended in many medical centers. Tumor growth patterns in ICC can be mass-forming, periductal infiltrating or mixed. Mass-forming ICC is seen most frequently [11]. FDG involvement is less in infiltrating tumors, making it less helpful to show the tumor in imaging techniques [12].

Surgery is the only method of treatment that is likely to cure ICC. However, because ICC is a disease that tends to exhibit late clinical presentation and early lymph node and distant metastasis, less than 1/3 of the patients with ICC are eligible for resection at the time of diagnosis. However, even in patients that are able to undo resection, ICC is a disease with poor prognosis and a low ratio of 5-year overall survival (OS) [13].

Positive surgical margin, large tumor size, multiple tumors, lymph node metastasis and vascular invasion were found to be factors associated with the poorer prognosis in resectable patients [14-16]. In patients who do not have surgical or other localized treatment options, systemic chemotherapy is the standard treatment [17]. However, prognostic factors are not clear for patients with advanced disease who do not have the ability to undergo surgical operation.

In many tumors, there are studies demonstrating the effect of pretreatment of FDGPET metabolic parameters on prognosis. However, there are a small number of studies that research the effects of FDG-PET metabolic parameters on the prognosis in patients with advanced ICC. Maximum standardized uptake values (SUVmax) reflect the maximum glucose metabolism measured at the highest pixel within the drawn field of interest. However, SUVmax does not show the total 18F-FDG retainment of the tumoral mass. While SUV values exhibit metabolic activity per gram of the tissue, they do not completely reflect the tumor's general metabolic activity. The size of a tumor can become larger or smaller without a change in metabolic activity per gram of the tissue. It is thought that functional tumor characterization is better made by means of total lesion glycolysis (TLG) parameter. TLG is

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calculated taking into consideration both the metabolic tumor volume and the average activity concentration of the tumor. Metabolic tumor volume (MTV) shows the total tumor volume that is drawn according to a certain threshold value. Volumetric measurement of tumor cells having high glycolytic activity is represented. Theoretically, the TLG parameter obtained from MTV and SUV mean measurements is accepted as a valuable parameter that reflects tumor biology because it shows both the volumetric and metabolic condition of the tumor. MTV and TLG measurements are determined by considering the values between 40-50% of the tumor's highest FDG retainment value as the threshold values. The clinical superiority of these parameters compared to SUVmax values, which provide information about the total metabolic activity of the tumor, has been reported in previous studies [18-21].

We aimed to investigate the relationship between FDG-PET metabolic parameters (SUVmax, TLG, and MTV) and survival in advanced ICC, which is a group of disease in which prognostic factors are not clear.

Materials and Methods

The medical records of 50 advanced ICC cases from Istanbul Bilim University Medical Oncology Clinic between 2012 and 2018 were reviewed retrospectively. All cases were diagnosed histopathologically and had FDG-PET/CT prior to systemic treatment. The relationship between patient survival, demographic characteristics and FDG-PET/CT metabolic parameters (SUVmax, MTV, and TLG) was analyzed. The institutional review board of this hospital approved our study, and informed consent was waived due to retrospective study design.

FDG-PET/CT imaging was performed by means of a PET scanner integrated with CT with 16 sections (PET/CT scanner (Discovery İQ; GE Healthcare, CA, USA). Patients fasting for 4 hours at a minimum who had a blood sugar level lower than 150 mg/dl were injected 444–629 MBq (12-17 mCi) 18F-FDG through IV routes. Patients rested in an available room for 1 hour so that biodistribution of the radiopharmaceutical was completed after FDG injection, evacuated their urinary bladder and then put to FDG-PET/CT scanner bed. First, a topogram was obtained; subsequently, IV unenhanced low dose CT images of the region comprising proximal vertex femur were obtained as well as PET images of the same region. Visual assessment and interpretation of the images was conducted by two doctors, and quantification of 18F-FDG-PET/CT data was made by one doctor. Regions that exhibited increased 18F-FDG retainment more intensively than surrounding tissues and that were not considered physiological retainment were evaluated as positive. SUVmax and SUVmean values in the volume of interest drawn around the primary tumor were recorded. The MTV value was determined using the help of commercial company software after regions of interest (ROI) drawing around the tumor. A workstation to automatically calculate the MTV and TLG. MTVs were defined as the tumor volume inside the tumor boundaries using SUV thresholds that were 40% of the tumor SUVmax. TLGs were calculated by multiplying the mean SUV by the tumor volume inside the tumor boundaries. The TLG value was obtained by multiplication of the MTV value with the SUVmean value.

Descriptive statistical data, including mean, standard deviation, median, minimum and maximum, were used to describe continuous variables. Survival analysis was performed using the Kaplan-Meier method. Comparisons of median survivals among groups were examined with log-rank test. Cox regression analysis was conducted as a survival analysis for continuous parameters. For parameters found to be significant in univariate analysis, Cox regression analysis was performed as a multivariate analysis. The statistical significance level was determined to be 0.05. Analyses were carried out using MedCalc Statistical Software version 12.7.7 (MedCalc Software bvba, Ostend, Belgium, 2013).

Results

Fifty patients diagnosed with advanced, inoperable ICC with systemic treatment participated in the study. Thirty-two (64.0%) patients were male, and 18 (36.0%) patients were female. The average age of the participants was 59.3±13.2 years old. The number of patients with extrahepatic metastasis was 14 (28%) and 36 (72%) without extrahepatic metastasis. Of the patients with extrahepatic metastasis, the lymph node was positive in 26% of them and negative in 74% of them. Thirty-five (70%) patients received gemcitabine-cisplatin chemotherapy as the first-line systemic treatment, 8 (16%) patients received gemcitabine-oxaliplatin (GemOx) chemotherapy, and 7 (14%) patients received other chemotherapy regimens. Transarterial radioembolization (TARE) could be applied to 16 (32%) patients who also subsequently received systemic treatment. Thirty (60%) patients died by the end of the follow-up (Table 1)

The measurements for the primary tumor prior to systemic treatment were as follows: FDG-PET SUVmax median value of 7.8, MTV of 177.7, and TLG of 350.8 (Table 2).

The median progression-free survival (PFS) was 6.5 months, and the OS was 13 months in the whole population of this study. There were no statistically significant differences in OS and PFS according to the first-line systemic treatment choice, lymph node metastasis positivity, presence of extrahepatic metastasis, whether or not TARE was applied and sex.

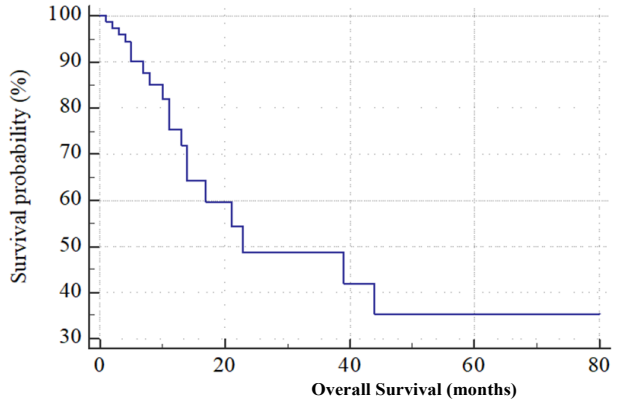
Each 1 unit of increase in MTV increases death risk by 1.0057 times. The Cox regression model for MTV values was found to be significant ($p<0.01$) (Figure 1). The Cox regression model for SUVmax values was not found to be significant ($p=0.308$). Each 1 unit of increase in TLG increases the risk of death by 1.0034 times. The Cox regression model for TLG values was found to be significant ($p<0.013$) (Figure 2), and the results are presented in Table 3.

		N	%
Sex	Male	32	64.0
	Female	18	36.0
Extrahepatic metastasis	Present	14	28.0
	Not Present	36	72.0
Serial Systemic Treatment	Gemcitabine-Cisplatin	35	70.0
	GemOx	8	16.0
	Other	7	14.0
Lymph Node Metastasis	Yes	5	10.0
	No	14	28
TARE applied	Yes	16	32.0
	No	34	68.0
Vital Status	Alive	30	60.0
	Expired	20	40.0

Table 1: Demographic characteristics.

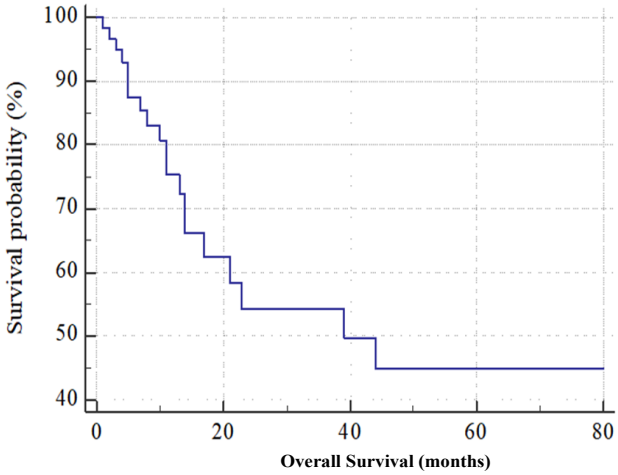
	Average ± SS	Median (Min-Max)
Pretreatment SUVmax	8.6±2.9	7.8 (3.05-14)
Metabolic Tumor Volume	186.5±133.3	177.7 (18.1-716)
Total Lesion Glycolysis	369.9±167.8	350.8 (76.4-861.9)

Table 2: PET metabolic parameters.



Note: OS curve based on mean MTV values

Figure 1: Survival based on mean metabolic tumor volume.



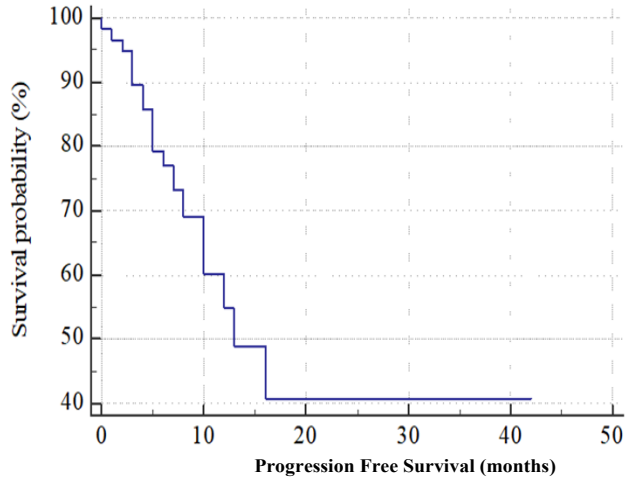
Note: OS curve based on mean TLG values.

Figure 2: Survival based on mean total lesion glycolysis.

Metabolic Tumor Volume	HR	95% Lower CI	95% Upper CI	p
	1.0057	1.0029	1.0085	**<0.001**
Pretreatment PET SUVmax	**HR**	**95% Lower CI**	**95% Upper CI**	**p**
	1.0874	0.929	1.2729	**0.299**
Total Lesion Glycolysis	**HR**	**95% Lower CI**	**95% Upper CI**	**p**
	1.0034	1.0009	1.0059	**0.007**

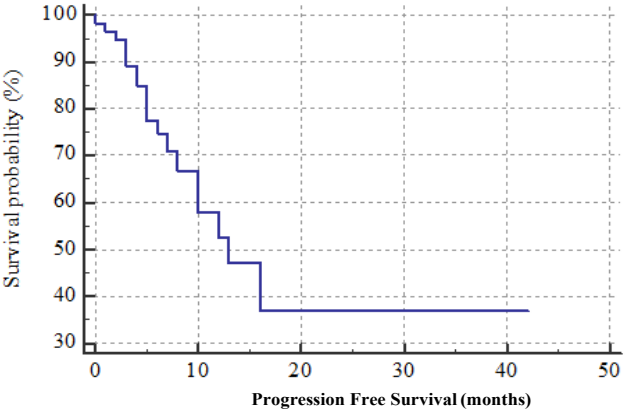
Table 3: Increase in death risk based on changes in metabolic parameters.

Each 1 unit of increase in MTV increases the risk of progression risk by 1.0038 times. The Cox regression model for MTV was found to be significant ($p<0.013$) (Figure 3). Each 1 unit of increase in pretreatment PET SUVmax increases the progression risk by 1.2148 times. The Cox regression model for changes in SUVmax was found to be significant ($p<0.029$) (Figure 4). Each 1 unit of increase in the TLG increases progression risk by 1.0043 times. The Cox regression model for TLG was found to be significant ($p=0.001$) (Figure 5), and the results are presented in Table 4.



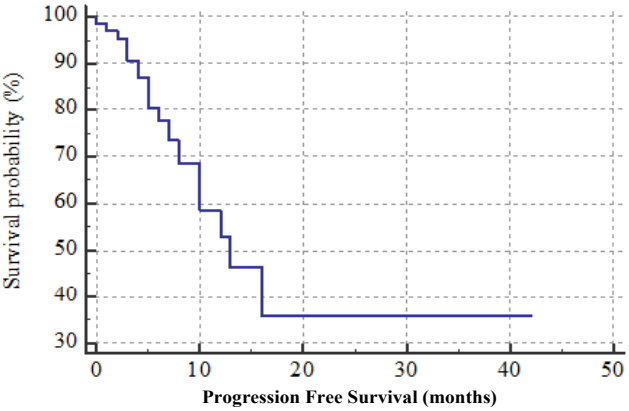
Note: PFS curve based on mean MTV values.

Figure 3: Survival based on mean metabolic tumor volume.



Note: PFS curve based on mean SUVmax values.

Figure 4: Survival based on mean pretreatment FDG-PET SUVmax.



Note: PFS curve based on mean TLG values.

Figure 5: Survival based on mean total lesion glycolysis.

Metabolic Tumor Volume	HR	95% Lower CI	95% Upper CI	p
	1.0038	1.0012	1.0064	**0.004**
Pretreatment PET SUVmax	**HR**	**95% Lower CI**	**95% Upper CI**	**p**
	1.2148	1.0277	1.4361	**0.023**
Total Lesion Glycolysis	**HR**	**95% Lower CI**	**95% Upper CI**	**p**
	1.0043	1.0019	1.0066	**<0.001**

Table 4. Increase in progression risk based on changes in metabolic parameters.

Discussion

Cholangiocarcinomas are rare cancers, and ICC is the rarest subtype. For this reason, studies involving only the ICC cases are extremely limited. The guiding information about the ICC usually comes from studies involving all of the biliary system tumors. Since the multidisciplinary tumor council at this hospital is considered the reference center on liver tumors for the region, patients with ICC are seen relatively more often at our hospital. Therefore, we wanted to investigate the role of FDG-PET/CT on the prognosis of this rare cancer.

Systematic chemotherapy is superior to BSC in inoperable, advanced-stage ICC [17]. However, survival with systemic chemotherapy alone is short. In advanced-stage ICC, after the ABC-2 study, which was the only randomized phase III study in this group of patients, cisplatin-gemcitabine treatment became the standard treatment, and systemic chemotherapy alone was recommended at the category 1 level in the guidelines [22]. Because survival with chemotherapy alone is not long, in recent years, for ICCs with inoperable but nonliver metastases, systemic treatment with concurrent transarterial radioembolization (TARE) treatment was a treatment option. TARE, or in other words Yttrium-90 (Y90) selective internal radiotherapy (SIRT), is a minimally invasive, imageguided procedure carrying millions of small beta-emitting Y90 microspheres to the tumor in the liver via a microcatheter placed into the hepatic artery. In local advance nonmetastatic irresectable ICC, there are prospective studies on the effectiveness of systemic chemotherapy combined with TARE treatment [23-25]. There are also retrospective studies of TARE+systemic treatment, apart from prospective phase II trials. In a retrospective study with data from 14 patients from our clinic, the median PFS and OS of patients who underwent systemic chemotherapy and TARE with inoperable but nonliver metastasis were superior to those reported in the literature who underwent chemotherapy alone [26]. However, the questions that remain include whether every advanced-stage patient should be treated with TARE in addition to systemic treatment, after determining prognostic factors, or combined treatment modalities should be decided based on prognosis.

SUVmax was measured in many tumors, including lung, stomach and renal cell cancers, and 18F-FDG-PET retention was associated with prognosis [27-31]. Many studies have shown the prognostic significance of FDG-PET in biliary cancers [8,32,33]. In addition, there are reports showing the relation of PET parameters, such as MTV and TLG, with prognosis, indicating tumor burden in head and neck cancer and lung cancer [34,35]. However, few studies have investigated the relationship between prognosis and other metabolic parameters, except SUVmax, which included only patients with ICC.

In a retrospective study carried out by Furukawa et al. [36] in BTC, which included many operated patients, the authors analyzed whether FDG-PET and high FDG retention affected the general survival independent of the clinicopathologic features of the tumor. It was concluded that the prognosis of patients with a high SUVmax value was worse than those with a low SUVmax value [36]. In a retrospective study carried out by Cho et al. [33] in 106 patients with unresectable BTC, 53 patients with ICC, 30 patients with gallbladder cancer, 16 patients with ampulla vater cancer, and 7 patients with extrahepatic BTC, the authors analyzed whether SUVmax was a prognostic factor for survival. Based on the results of this study, ICC had the shortest OS duration and the highest SUVmax values, while ampulla vater tumors had the longest OS duration and the lowest SUVmax values. Additionally, when analyzed separately for each tumor type, there was a significant difference in OS compared to SUVmax in gallbladder tumors and ampulla vater tumors. In ICC, no relationships were found between OS and SUVmax values. In a retrospective study carried out with sixty-six patients with extrahepatic and intrahepatic cholangiocarcinoma (59.1% with ICC), it was concluded that a high preoperative SUVmax value was an independent poor prognostic factor [37].

Even though there are very few studies, apart from our study, on the prognostic importance of FDG-PET in BTC patients, there is a retrospective study on a group that included only ICC patients [38]. In this study, many of these cases included advanced-stage ICC patients (78.9%) in addition to patients with operable cancer. According to this study, high SUVmax, high SUVpeak, and high SUVmean values were significantly related to shorter OS. There were no significant effects of TLG and MTV on prognosis.

In a very new study, the authors analysed the prognostic impact of metabolic parameters of FDG-PET in 24 patients with ICC undergoing hepatic resection [38]. They reported that, patients with high SUVmax, high MTV or high TLG had a significantly worse prognosis.

In our study, 50 ICC patients were analyzed, and all of them had advanced-stage ICC and were under systemic treatment. The number of patients with nonliver metastasis was 14 (28%), and the number of patients without nonliver metastasis was 36 (72%). The effect of SUVmax, MTV, and TLG parameters of FDG-PET/CT on prognosis was investigated. According to the Cox regression models, each unit increase in MTV and TLG led to a significant increase in the risk of death; in addition to MTV and TLG, each unit increase in SUVmax also led to a significant increase in the risk of progression. Based on these conclusions, we conclude that if SUVmax, MTV, and TLG FDG-PET parameters from primary tumors before treatment are high, then this fact is related to a poor course of disease and a shorter lifespan. Apart from FDG-PET metabolic parameters, it was not determined whether the nonliver metastasis at the beginning, the existence of lymph node metastasis, the first series systemic treatment preference, and the effect of conformity of TARE with the disease affected the prognosis.

Considering previous studies on the subject, these results suggested that pretreatment FDG-PET/CT contributes to staging in advanced ICC patients and guides the prediction of prognosis. We think that in the prediction of the prognosis in this patient group, which is rarely seen and therefore treatment options are limited, will guide clinicians in shaping the treatment. In addition to routinely measured SUVmax values, we also demonstrated that metabolic parameters, such as MTV and TLG, contribute to the prognosis, and routine measurements of these parameters will be beneficial.

There are some limitations of our study. Firstly, cox regression analysis is significant, but hazard ratio is not very high. More clear results can be obtained in a more homogenous group with higher patient numbers. Secondly, we add inoperable patients to the study, it includes both patients with inoperable liver only disease and

extrahepatic metastasis. Perhaps a study with only locally advanced patients will be more guiding the addition of local treatments. Also, this was a retrospective single-center study, and thus the results might be subject to selection bias. Further studies are needed to elucidate the prognostic values of volumetric PET/CT parameters.

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