Korean J Gastroenterol Vol. 62 No. 4, 227-233
http://dx.doi.org/10.4166/kjg.2013.62.4.227
pISSN 1598-9992 eISSN 2233-6869

ORIGINAL ARTICLE

KJG

담도암 및 담낭암 환자에서 ^{18}F-Fluorodeoxyglucose 양전자방출단층촬영으로 측정한 원발 종양 최대 표준화섭취계수의 생존에 대한 예후적 가치

이지용, 김홍주, 임서형, 신동석, 유정희, 주덕윤, 박정호, 박동일, 조용균, 손정일, 전우규, 김병익
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Primary Tumor Maximum Standardized Uptake Value Measured on ^{18}F-Fluorodeoxyglucose Positron Emission Tomography-Computed Tomography Is a Prognostic Value for Survival in Bile Duct and Gallbladder Cancer

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Background/Aims: Few studies have assessed the prognostic value of the primary tumor maximum standardized uptake value (SUV_{max}) measured by 2-[^{18}F]-fluoro-2-deoxy-D-glucose PET-CT for patients with bile duct and gallbladder cancer.
Methods: A retrospective analysis of 61 patients with confirmed bile duct and gallbladder cancer who underwent FDG PET-CT in Kangbuk Samsung Medical Center (Seoul, Korea) from April 2008 to April 2011. Prognostic significance of SUV_{max} and other clinicopathological variables was assessed.
Results: Twenty-three patients were diagnosed as common bile duct cancer, 17 as hilar bile duct cancer, 12 as intrahepatic bile duct cancer, and nine as gallbladder cancer. In univariate analysis, diagnosis of intrahepatic cholangiocarcinoma and gallbladder cancer, mass forming type, poorly differentiated cell type, nonsurgical treatment, advanced American Joint Committee on Cancer (AJCC) staging and primary tumor SUV_{max} were significant predictors of poor overall survival. In multivariate analysis adjusted for age and sex, primary tumor SUV_{max} (hazard ratio [HR], 4.526; 95% CI, 1.813-11.299), advanced AJCC staging (HR, 4.843; 95% CI, 1.760-13.328), and nonsurgical treatment (HR, 6.029; 95% CI, 1.989-18.271) were independently associated with poor overall survival.
Conclusions: Primary tumor SUV_{max} measured by FDG PET-CT is an independent and significant prognostic factor for overall survival in bile duct and gallbladder cancer. **(Korean J Gastroenterol 2013;62:227-233)**

Key Words: Prognosis; Fluorodeoxyglucose F18; Positron-emission tomography and computed tomography; Bile duct neoplasms; Gallbladder neoplasms

INTRODUCTION

The diagnosis of bile duct and gallbladder cancer is difficult and the prognosis of both types of cancer is poor.[1] The overall 5-year survival rate of gallbladder cancer is <5%, and the natural history of unresectable cholangiocarcinoma results in no survival at year 5.[2-4] Currently, only surgical resection with appropriate lymph node dissection remains as

Received June 22, 2013. **Revised** August 8, 2013. **Accepted** August 9, 2013.

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Financial support: None. Conflict of interest: None.

the curative approach in some patients.[5-7] An extensive work-up that includes diagnostic imaging modalities, such as ultrasonography, CT, MRI, and endoscopic measures, is essential for accurate tumor staging and treatment decisions.[8] However, differential diagnosis based solely on structural imaging information remains challenging because of its variable reliability and lack of information on its effect on predicting and improving prognosis.

2-[^{18}F]-Fluoro-2-deoxy-D-glucose (FDG) PET-CT that provides metabolic and anatomic information of malignant cells simultaneously is a relatively new and accurate diagnostic approach in various malignancies. Several studies have described the usefulness of PET-CT in the detecting and staging of bile duct and gallbladder cancer.[8-10] In these studies, the FDG PET-CT measured the maximum standardized uptake value (SUV_{max}), a semiquantitative simplified measurement of tissue deoxyglucose metabolic rate. A few retrospective studies have explored the survival prognostic significance of the primary tumor SUV_{max} in various malignancies.[11-13] In bile duct and gallbladder cancer, fewer studies have been conducted to evaluate the prognostic value of primary tumor SUV_{max} and most of these reports included only a small number of patients.[14-16]

So, we performed a retrospective analysis from prospective data to determine the prognostic value of primary tumor SUV_{max} for patients with bile duct and gallbladder cancer.

MATERIALS AND METHODS

1. Patients

Sixty-one patients who were diagnosed with bile duct and gallbladder cancer and underwent FDG PET-CT in Kangbuk Samsung Medical Center (Seoul, Korea) from April 2008 to April 2011 were included in this study. The prospectively collected data and medical records of each patient were reviewed retrospectively. The diagnosis of bile duct and gallbladder cancer was confirmed by pathological analysis of surgical specimens in resectable patients (n=16) and pathological specimens that obtained from percutaneous biopsy or endoscopic biopsy (n=29) or clinical follow-up (n=16) in unresectable patients. Bile duct cancer was classified as intrahepatic, hilar or extrahepatic lesions according to the site of lesion shown on conventional imaging including multidector row CT (MDCT), MRCP, ERCP or EUS. All cancers were classified according to their morphologic features revealed by imaging as mass-forming, periductal infiltrating, or intraductal-growing type.[17] Histologic typing was classified as well, moderately, or poorly differentiated according to the World Health Organization classification.[18] Staging criteria were based on the clinical staging system of the American Joint Committee on Cancer (AJCC) TNM classification.[19] We also classified AJCC staging as early (I, II) and advanced (III, IV) stage. Treatment method was classified as surgical treatment in cases of curative surgery and non-surgical treatment in cases of exploratory laparotomy and palliative treatment. We considered the patient with fever (body temperature >38°C) or laboratory evidence of inflammatory response (white blood cell count >10 or <4×10^9/L, or CRP $\geq$1 mg/dL), accompanied by jaundice (total bilirubin $\geq$2 mg/dL) or abnormal liver function tests (when serum AST, ALT, ALP and GGT levels are more than 1.5 times of upper normal limits) 24 hours before and after performing PET-CT, as cholangitis patient.[20] The institutional review board approved this retrospective study and waived patient consent for this specific study (KBC13065).

2. FDG PET-CT

All patients fasted for at least 6 hours before ^{18}F-FDG PET-CT. The blood glucose level was checked before ^{18}F-FDG administration and the patient was rescheduled if the blood glucose level exceeded 130 mg/dL. A range of 370-555 MBq for ^{18}F-FDG was injected intravenously. Scanning began 60 minutes later after voiding. No intravenous contrast agent was used for the CT scans. Imaging and data acquisition were performed using a Discovery STE combined PET-CT system (General Electric Medical Systems, Milwaukee, WI, USA). A PET scanner composed of 13,440 bismuth germinate crystals arranged in 24 rings, integrated with a 16 multislice helical CT scanner, acquired the co-registration of the PET and CT images in one session. A total of 6-8 bed positions were available, and the acquisition time per bed position was 2 minutes. All patients were examined in the supine position with their arms raised. The PET-CT images were reconstructed using iterative reconstruction with two iterations and 14 subsets, resulting in 47 two-dimensional sections spaced 3.27 mm apart, over each axial field-of-view increment of 157 mm. The attenuation-corrected PET images, CT images, and co-registered PET-CT images were analyzed si-

multaneously by a board-certified nuclear medicine physician on an eNTEGRA workstation with viewing-dedicated software (ELGEMS, Haifa, Israel). Image interpretation was based on identifying regions with increased FDG uptake on PET images and the anatomic delineation of all FDG-avid lesions on the coregistered PET-CT images. Tumors were defined as positive FDG uptake if the radioactivity of the tumor was higher than that of the surrounding liver tissue in the visual analysis. Images of each biliary tumor were assessed semiquantitatively by measuring and calculating the SUV_{max} normalized to lean body mass. The SUV_{max} was calculated for the quantitative analysis of tumor ^{18}F-FDG uptake, as follows: SUV_{max}=C (kBq/mL)/ID (kBq)/body weight (kg) where C is the tissue activity concentration measured by PET and ID is the injected dose. All CT images were viewed separately to identify additional lesions without FDG uptake using soft tissue, lung, and bone window leveling.

3. Statistical analyses

Patients were stratified and analyzed using with regard to sex, age, diagnosis, morphological feature, histologic typing, treatment method, AJCC stage, primary tumor size and primary tumor SUV_{max}. To increased statistical power, we subgrouped AJCC stage as early (I, II) and advanced (III, IV), and treatment as surgical (curative surgery) and non-surgical (exploratory laparotomy and palliative treatment). The Youden index was used to determine the cutoff value of SUV_{max} that yielded the optimal sensitivity and specificity. Survival time was defined as the time interval from the date of pathologic diagnosis or clinically confirmed diagnosis until death or the last follow-up date. Overall cumulative survival was analyzed by the Kaplan-Meier method, and univariate analysis was performed with a log rank comparison. A value of $p<0.05$ was considered to be statistically significant. Variables with $p<0.05$ in univariate analysis of factors affecting survival were included in a subsequent multivariate analysis, using a Cox proportional hazard regression analysis. The relationship between primary tumor SUV_{max} and cholangitis was analyzed by Fisher's Exact test. All statistical analyses were performed using IBM SPSS Statistics ver. 18.0 (IBM, Armonk, NY, USA).

RESULTS

1. Characteristics of all patients

The patient characteristics are summarized in Table 1. Twenty-nine (47.5%) patients were female. Final diagnosis was confirmed by curative resection, percutaneous and/or endoscopic biopsy, and follow-up in 16 (26.2%), 29 (47.5%) and 16 (26.2%) patients, respectively. Fourteen (23.0%) patients received with curative surgery, three (4.9%) patients received exploratory laparotomy and 44 (72.1%) patients were palliatively treated. No patient had cancer with intraductal growing morphology. Seven (11.5%) patients who had cholangitis at 24 hours before and after undergoing PET-CT. The Youden index showed that the optimal cutoff value of primary tumor SUV_{max} for predicting survival was 5.5. Using primary tumor SUV_{max} of 5.5 yielded a sensitivity 69.2% and a specificity 77.3%. There was no significant association between primary tumor SUV_{max} and cholangitis (p=0.699).

Table 1. Baseline Clinicopathologic Characteristics of the Patients

Characteristic	Data
Total number	61 (100.0)
Age (yr)	68.5±8.9
Gender (male)	32 (52.5)
Final diagnosis	
CBDC	23 (37.7)
Hilar	17 (27.9)
IBDC	12 (19.7)
GBC	9 (14.8)
Morphologic type	
Mass forming	31 (50.8)
Periductal infiltrating	30 (49.2)
Intraductal growing	0 (0)
Tumor differentiation	
Well differentiated	16 (45.7)
Moderately differentiated	13 (37.1)
Poorly differentiated	6 (17.1)
AJCC stage	
Early (I/II)	49 (80.3)
Advanced (III/IV)	12 (19.7)
Primary tumor size (cm)	4.3±3.1
Diagnostic sensitivity of FDG PET-CT	51 (83.6)
SUV_{max} of primary tumor	6.4±4.6
Cholangitis	7 (11.5)

Values are presented as mean±SD or n (%).
CBDC, common bile duct cancer; IBDC, intrahepatic bile duct cancer; GBC, gallbladder cancer; AJCC, American Joint Committee on Cancer; FDG PET-CT, 2-[^{18}F]-fluoro-2-deoxy- D-glucose PET-CT; SUV_{max}, maximum standardized uptake value.

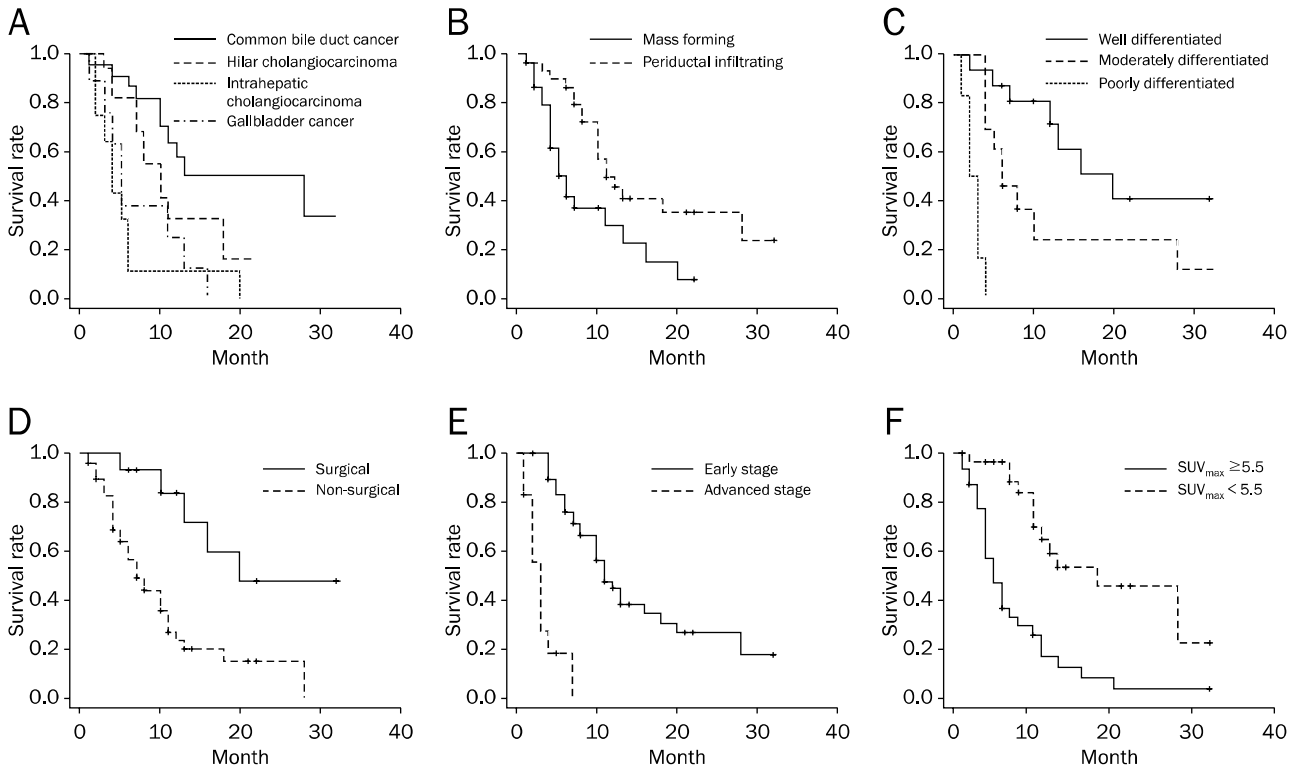

Fig. 1. Univariate analysis of the patient population, tumor characteristics, and overall survival. Kaplan-Meier survival curves with log rank comparisons between each group of final diagnosis (A), morphological type (B), histologic grade (C), treatment method (D), American Joint Committee on Cancer stage (E) and primary tumor standardized uptake value (SUV_{max}) (F). Log rank p-values were <0.05 for each comparison, respectively.

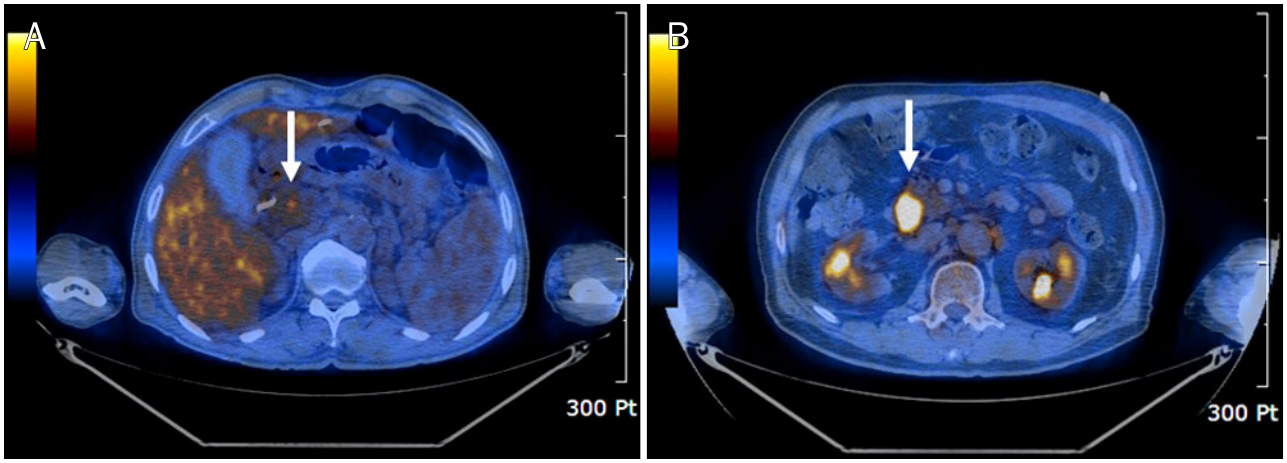

Fig. 2. Axial FDG PET-CT images of two patients with common bile duct cancer who received nonsurgical treatment. Primary tumor maximum standardized uptake value is 3.1 (arrow) in 69-year-old man who was alive 26 months after diagnosis (A), and 9.9 (arrow) in 76-year-old man who died 10 months after diagnosis (B), respectively.

2. Prognostic factors of bile duct and gallbladder cancer

In all 61 patients, the overall median survival was 10.0 months (95% CI, 7.39 -12.60). In univariate analysis with log rank comparisons, diagnoses of intrahepatic bile duct cancer (IBDC) (p<0.001) and gallbladder cancer (p=0.004), mass forming type (p=0.009), poorly differentiated cell type (p<0.001), nonsurgical treatment (p=0.004), advanced

stage (p<0.001), and higher primary tumor SUV_{max} than 5.5 (p<0.001) were significant associated factors of poor overall survival (Figs. 1, 2). However, primary tumor size (p=0.104), age (p=0.087) and sex (p=0.268) were not significantly associated with overall survival.

3. Primary tumor SUV_{max} is an independent prognostic factor of bile duct and gallbladder cancer

In Cox proportional hazard regression analysis, primary tumor SUV_{max} (hazard ratio [HR], 4.526; 95% CI, 1.813-11.299; p=0.001) was an independent and significant predictive factor associated with poor overall survival, regardless of age, sex, morphological feature, AJCC stage or treatment. Advanced stage (HR, 4.843; 95% CI, 1.760-13.328; p=0.002) and nonsurgical treatment (HR, 6.029; 95% CI, 1.989-18.271; p=0.001) were also independent prognostic factors of overall survival, too (Table 2). Whereas mass-forming morphological feature was not an independent significant variable for predicting poor prognosis.

DISCUSSION

The usefulness of FDG PET-CT is not confined to diagnosing and staging cancers, but extended to the evaluation of the proliferative activity and/or malignant potential of tumors that influence prognosis. Several studies involving detecting, staging, and differentiating tumors have been conducted for bile duct and gallbladder cancer,[8-10] but these did not fully assess the prognostic significance of this technique.

The results of our study show that a high FDG uptake in the primary tumor, measured by FDG PET-CT, was independently correlated with poor overall survival in patients with all types of bile duct and gallbladder cancer. The advanced clinical stage and nonsurgical treatment were also independent and

Table 2. Cox Proportional Hazard Regression Analysis of Factors Associated with Overall Survival of Bile Duct and Gallbladder Cancer

Factor	Patient (n)	Unadjusted			Adjusted[a]		
		HR	95% CI	p-value	HR	95% CI	p-value
Primary tumor SUV_{max}							
<5.5	32	1			1		
≥5.5	29	3.927	1.968-7.836	<0.001	4.526	1.813-11.299	0.001
AJCC stage							
Early (I/II)	49	1			1		
Advanced (III/IV)	12	10.646	4.428-25.596	<0.001	4.843	1.760-13.328	0.002
Treatment							
Surgical	14	1			1		
Nonsurgical	47	4.053	1.559-10.537	0.004	6.029	1.989-18.271	0.001
Morphology							
Mass forming	31	1			1		
Periductal infiltrating	30	0.418	0.217-0.803	0.009	0.828	0.335-2.050	0.684
Age (yr)							
≥65	41	1			1		
<65	20	0.544	0.262-1.128	0.102	1.017	0.976-1.061	0.417
Sex							
Male	32	1			1		
Female	29	1.424	0.744-2.726	0.286	1.19	0.566-2.504	0.646
Diagnosis							
CBDC	23	1					
Hilar	17	2.159	0.889-5.242	0.089			
IBDC	12	6.354	2.520-16.019	<0.001			
GBC	9	4.153	1.585-10.883	0.004			
Histology							
Well	16	1					
Moderate	13	2.651	0.979-7.182	0.055			
Poor	6	27.532	6.494-116.730	<0.001			

HR, hazard ratio; SUV_{max}, maximum standardized uptake value; AJCC, American Joint Committee on Cancer; CBDC, common bile duct cancer; IBDC, intrahepatic bile duct cancer; GBC, gallbladder cancer.
[a]Multivariate analysis.

significant predictors of survival on multivariate analysis.

There is a possibility of inflammatory effect because the coexisting active inflammatory condition can result in a false-positive FDG uptake.[9] In the present study, we found no significant correlation between primary tumor SUV_{max} and presence of cholangitis at the time of performing PET-CT. Kitamura et al.[15] reported there are no marked inflammatory effect on FDG uptake in patients with extrahepatic bile duct cancer.

Various studies have assessed whether the primary tumor SUV_{max} can be used to predict the survival of patients with other malignancies. In lung cancer, breast cancer, malignant lymphoma, endometrial cancer and early cervical cancer, studies showed that primary tumor SUV_{max} on FDG-PET was an independent and significant prognostic value on multivariate analysis.[11-13,21-23] A similar study evaluated the correlation between FDG uptake and prognosis for patients with bile duct and gallbladder cancer.[14] The results showed that high SUV_{max} was associated with poor overall survival on univariate analysis but was not independently associated with prognosis on multivariate analysis. Kitamura et al.[15] reported that SUV_{max} on FDG PET is an independent predictor of survival in patients with extrahepatic bile duct cancer on multivariate analysis. Seo et al.[16] described that SUV_{max} is a significant predictor of disease free survival, not overall survival, for patients with mass-forming IDBC. In all of these studies, SUV_{max} was evaluated solely by FDG PET. Our study is the first to measure SUV_{max} by FDG PET-CT; the results reveal the independent and significant correlation between primary tumor SUV_{max} and overall survival in all types of bile duct and gallbladder cancer.

The association of high FDG uptake with poor prognosis may occur because FDG accumulates more in metabolically active cells with aggressive malignant potential. In bile duct cancer, FDG accumulation appears primarily to result from the increased expression of glucose transporter, especially glucose transporter-1 (Glut-1).[24] The overexpression of Glut-1 is associated with depth of invasion and increased incidence of lymph node and hepatic metastasis in colorectal cancer,[25] increased proliferation of glioma[26] and worsened prognosis in non-small cell lung cancer.[27] However, no report has assessed the association of up-regulation of Glut-1 with the prognosis in bile duct and gallbladder cancer. Further study is needed to clarify the relationship between the overexpression of Glut-1 and cell proliferation, malignant potential, and prognosis of bile duct and gallbladder cancer.

Increased FDG uptake may be associated with advanced stage. Some authors reported that a high SUV_{max} of primary tumors is significantly related to higher stage in various cancers.[12,22,23,25] In bile duct cancer, one study reported a significant association between high SUV_{max} and advanced pathologic stage.[14] In this study, the pathologic stage was also independently associated poor overall survival in multivariate analysis. However, in our study, high SUV_{max} was associated with poor overall survival regardless of advanced stage in multivariate analysis.

Some evidence indicates that high FDG uptake is associated with recurrence in lung cancer and IBDC.[16,22] In mass-forming IBDC, the disease-free survival of patients with a high primary tumor SUV was significantly worse than those with a low SUV.[16] Although we have no more detailed information for postoperative recurrence in our study, recurrence might be a contributory factor of poor survival. Recurrent malignant cancer cells tend to be more aggressive and resistant to palliative treatment.

There are several limitations in this study. Although we used prospective database by using a single PET-CT instrument, this study is a retrospective study. We could not evaluate the prognostic value of primary tumor SUV_{max} for each types of final diagnosis because of the small number of included patients. Additional larger and prospective studies are needed to elucidate the clinical significance of FDG PET-CT and tumor SUV for bile duct and gallbladder cancer, and for each type of them.

In conclusion, primary tumor SUV_{max} measured using FDG PET-CT is an independent and significant prognostic factor for overall survival in patients with bile duct and gallbladder cancer. Prospective analyses with larger numbers of cases are warranted for confirmation.

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