Med. J. Cairo Univ., Vol. 88, No. 2, March: 787-796, 2020
www.medicaljournalofcairouniversity.net

The Effect of Esophageal Varices on the Outcome of Radiofrequency Ablation in Patients with Hepatocellular Carcinoma

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Abstract

Background: Little is known about the effect of esophageal varices on the outcome of radiofrequency (RF) ablation in patients with hepatocellular carcinoma (HCC).

Aim of Study: To determine the therapeutic efficacy of radiofrequency ablation of hepatocellular carcinoma associated with esophageal varices, and the important risk factors that affect the outcome.

Patients and Methods: 121 of 168 patients with portal hypertension had esophgeal varices, underwent RF ablation as a treatment for a single HCC ($\leq$ 5cm). Therapeutic efficacy was evaluated. Logistic regression analyses of risk factors for occurrence of complication and multivariate cox-regression analyses for overall survival were detected.

Results: Patients with HCC and esophageal varices had a complete ablation rate of 88.4%. Portal vein thrombosis was the most type of complication. By univariate analysis, thrombocytopenia (p=0.032) was independent risk factor of complications. By multivariate analysis, left lobe location of HCC (p=0.015) was independent risk factor of complications and subcapsular location of HCC (p=0.019), was independent prognostic factors for survival.

Conclusion: This current study has proven that patients with portal hypertension and esophageal varices can tolerate RF ablation of HCC. Dealing caution as regard correction of thrombocytopenia and professionally as regard location of HCC, we can improve the outcome of RF ablation.

Key Words: *Radiofrequency ablation – Hepatocellular carcinoma – Esophageal varices.*

Introduction

THE results of hepatocellular carcinoma (HCC) patients presenting with esophageal varices (EV) was significantly poor than that of the general HCC patients. This possibly to be defined by the more severe underlying cirrhosis and the higher frequency of advanced HCC with predominant portal vein thrombosis [1]. Surgical resection did not appear like a viable treatment option for this group of patients. It might consequently occur that trans-arterial chemoembolization (TACE) would possibly attempt some survival advantage to this precise organization of patients, supplied that their liver capabilities had been nonetheless reasonable and the portal vein changed into patent [2]. In previous studies, progression of HCC rather than complication of cirrhosis were the most cause of death in the long-term among the patients presenting with EV [3]. On different aspect, a history of recent variceal bleeding become often considered a contraindication for TACE for HCC in a few studies [4]. Liver transplantation is any other choice for affected patient with concurrent cirrhosis and HCC, the lack of donors and dropout from ready list continue to be the drawbacks of this treatment [5]. Percutaenous radiofrequency (RF) ablation treats HCC in a much targeted way [6]. Although esophageal EV have been incorporated into the Barcelona Clinic Liver Cancer (BCLC) staging system and is widely applied as important reference when selecting the treatment modalities in daily practice, to our knowledge, there has only been one study focusing on this group of patients, and revealed that the existence of EV may affect survival prognosis of HCC patients treated with RF ablation, but is not associated with hemorrhagic death [7].

Thus, the intention of this study was to assess the efficacy of RF ablation in patients with EV, as well as the prognostic elements for complications and survival effects.

Patients and Methods

Patients and selection criteria:

From July 2015 to March 2018, we enrolled 186 consecutive patients who developed first time

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HCC and underwent RF ablation therapy; 121 patients (91 males and 30 females; mean age 69.1±9.0 years; range 33-89 years), of them presenting with EV determined by upper gastrointestinal endoscope in the 3 months before treatment and had follow-up for over 6 months after treatment, and 47 patients (14 males and 13 females; mean age 65±8.0 years; range 35-75 years), without EV.

In our policy, RF ablation treatment is reserved for patients with good liver functions having single hepatic HCC (distance across ≤5cm), detected using at least two imaging tests, such as ultrasonography (US), tri-phasic computed tomography (CT), or dynamic magnetic resonance imaging (MRI), Fig. (1).

Exclusion criteria were as follows: (1) More than one HCC lesion or a single HCC ≥5cm in diameter, (2) Child-Pugh class C, (3) Presence of ascites, vascular tumor thrombosis, severe impaired coagulation (prothrombin time ratio <40% and platelet count <30,000/ μl), and concomitant severe cardiopulmonary disease.

Written informed consent was gained from all patients before RF ablation treatment. Treatment choice was embraced in the wake of taking the guidance of experienced advisors of specialists, oncologists and gastroenterogists.

Evaluation of esophageal varices:

Endoscopic findings of EVs were evaluated according to the general rules for the study of portal hypertension created by the Japan Society for Portal Hypertension [8]. With regard to the form (F) of EVs, no EV was considered as F0. A linear comparatively narrow EV was considered as Fl. A bead-shaped middle-Class EV was considered as F2, and tuberosity or a tumor-shaped EV was considered as F3. Red color sign were classified as positive or negative, Fig. (2). Patients with a positive red color sign were treated with endoscopic injection sclerotherapy or endoscopic variceal ligation before RF ablation. Pharmacotherapy including administration of a B-blocker against portal hypertension was not applied to any patients.

RF ablation procedures:

All RF techniques were led percutaneously under guidance of ultrasound, equivalent to depicted in past investigations [9]. RF ablation was performed using RITA (RITA Medical Systems, Angio Dynamics) system powered by 200 W generators. A 15-gauge multitined expandable electrode which could be sent up to 5cm was utilized in all techniques. RF Ablation procedures was carried out by one operator (M.I), and based on tumour size, and patient condition. The aim was to obtain complete ablation of HCC with safety margin of at least 0.5cm around the tumour. After RF ablation treatment, dynamic CT or MRI was performed within 2 weeks and when a residual HCC lesion was observed, RF ablation was performed again. Treatment was further repeated until confirmation of no residual HCC lesion was obtained. For follow-up, we performed CT or MRI every 3-4 months. When a recurrence was observed appropriate treatment was performed immediately.

Laboratory examinations:

Serum albumin, total bilirubin, and prothrombin activity were measured to establish Child-Pugh Classification, and Alpha-fetoprotein (AFP, Latex agglutination method) were assessed before RF ablation as tumor markers.

Post procedural follow-up:

Length of hospital stay after each RF ablation procedure did not exceed 24 hours to notice any kind of complications using all means available diagnostic methods, if indicated. Complications were defined as according to the recommendations of The Working Group on Image-Guided Tumor Ablation [10]. Major complication referred to those that lead to substantial morbidity and disability, increase the level of care, or result in hospital admission or substantially lengthens the hospital stay. All other complications were defined as minor.

The response to RF ablation was determined as incomplete or complete ablation based on US and triphasic CT examinations performed one month after each ablation procedure. Patients with a complete ablated HCC were subjected to follow-up program using ultrasound and tri-phasic CT examinations every 3-6 months.

HCC with incomplete ablation, defined as appearance of active tumor tissue adjacent to the ablated area were subjected to RF ablation provided that the availability of the same right circumstances. Distant tumour progression defined as, the emergence of one or several tumour(s) not adjacent to the ablation zone. The end point was the death or the date of the last follow-up or the date of the most recent follow-up visit.

Statistical analysis:

Continuous variables are shown as median values and as a range of minimum values and

maximum value. Nominal variables are shown in numbers and percentages, The Mann Whitney U test was used to compare continuous variables and the Chi-Square test or the Fisher exact test was used to compare nominal variables. Cumulative survival rates were analyzed using the Kaplan-Meier method, and statistical significance tests were conducted using the log-rank test. Factors related to survival prognosis were analyzed using univariate Cox proportional hazards regression models. Multivariate analysis was performed with factors that had a possibility of affecting survival added to the factors that were deemed significant as a result of the univariate analysis to calculate the adjusted relative risk odds ratios (OR) and 95% confidence intervals. A p-value of less than 0.05 was considered to be statistically significant. For statistical analyses we used SPSS for Windows 16.0 (SPSS Inc. Chicago, IL).

Results

Baseline characteristics:

The background characteristics of HCC and patients with and without EV who underwent RF ablation are shown in Table (1). The median tumor diameter was 40mm in both groups. Patients without EV who age ›_70 yr were statistically significantly higher than the EV group (p=.043).

There were no statistical significance between the two groups in terms of gender, etiology of cirrhosis, location of HCC (lobe & sub capsular), size of HCC, and laboratory findings (albumin, bilirubin, and ⟨x-fetoprotein). The degree of thrombocytopenia (p=0.025) and prothrombin activity (p=0.012) were more significant and worse toward the patients associated with EV.

Therapeutic response:

For the treatment of HCCs, Primary complete ablation was achieved in 107 HCCs (88.4%) of patients presenting with EV, and in 38 HCC (80.9%) of patients presenting without EV. There was no significant difference in the incidence of primary complete ablation rate between the two groups (p=0.15), Residual tumours treated by second session of RF ablation with secondary complete ablation success rate 100%. No patients received repeated RF ablation or still had residual tumor after re-ablation due to difficulty in ablation location, or poor function of the liver.

Complications:

A total of 17 (14%) complications were observed in patients presenting with EV during follow-up, see Table (2). No major complications were reported during any of the RF ablation procedures. All complications were minor and subsided naturally or after medication. There was no procedure-related death.

There was no significant difference in the overall incidence of complications between the two groups (EV=14% vs without EV=10.6%, p=0.3), except that portal vein thrombosis was significantly more common in the EV group (6% vs 0%, p=0.04), see Table (2), see Figs. (3,4).

The time interval between the RF ablation procedure and the development of portal vein thrombosis was 7-30 days (mean, 14 days), see Fig. (5). No patient required further treatment, as a result of thrombosis, see Fig. (6).

Univariate logistic regression analysis revealed that platelet count was independent prognostic factor for post RF ablation complication (p=0.03), and multivariate logistic analysis confirmed that platelet count was independent prognostic factor for complication (p=0.025), with odd ratio equal to 0.987 and confidence interval (0.975-998), see Table (4).

Overall accumulative survival and prognostic factors:

At the end of the study, 125 patients were alive, and 43 were dead. Follow-up period was 25.27 months (758 days) (median: 11.6 months). No patients were lost to follow-up (mean 11.9 months). Cumulative survival of subjects with EV was 77.7% in comparison to the survival rates of subjects without EV which were 66%. Causes of deaths were 13 related to HCC progression, 5 due to liver failure, and 14 were related to other causes in patients with EV On other side, the causes of deaths were 6 related to HCC progression, 5 due to liver failure, and 5 were related to other causes in patients without EV.

Results of the multivariate analysis of factors affecting survival using the Cox proportional hazards model showed that sub-capsular location (OR: 0.003; p=0.019) and the presence of EV were associated with a significant poor survival, see Table (5).

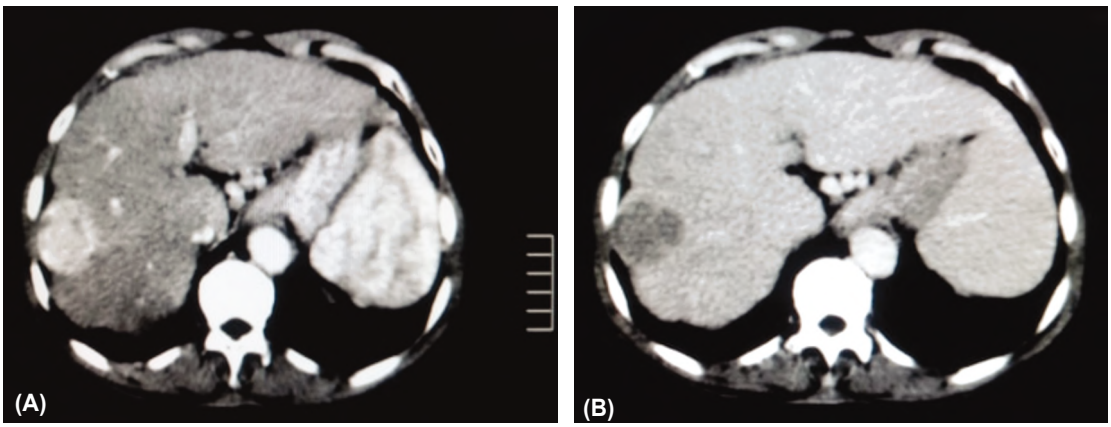

Fig. (1): Diagnosis of HCC. Computed tomographic scan of HCC shows contrast enhancement in the early arterial phase (A) and hypointensity in the portovenous phase (B).

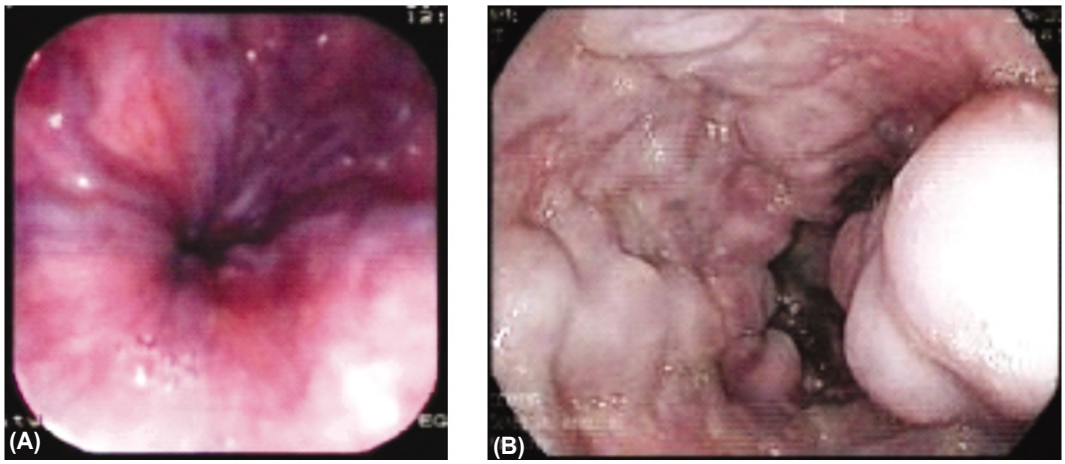

Fig. (2): (A) Esophageal varices of small size, bluish in color with few red color sign. (B) Esophageal varices of large size, white in color with few red color sign.

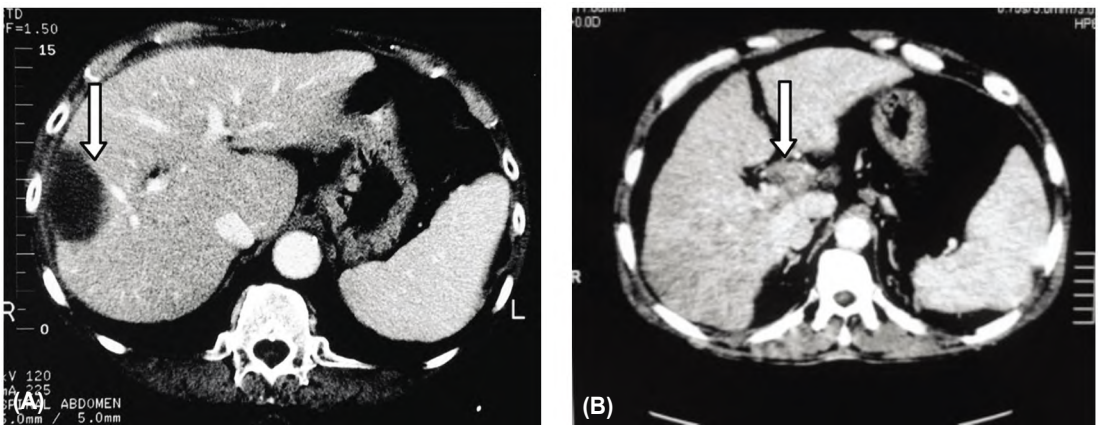

Fig. (3): (A) 57-year-old man with hepatocellular carcinoma in segment 8 that was treated by percutaneous radiofrequency ablation (RFA) (arrow). (B) Transverse helical portal venous phase CT scan obtained 1 month after RFA. Nonenhancing filling defect (arrow) is present in main portal vein, (arrow).

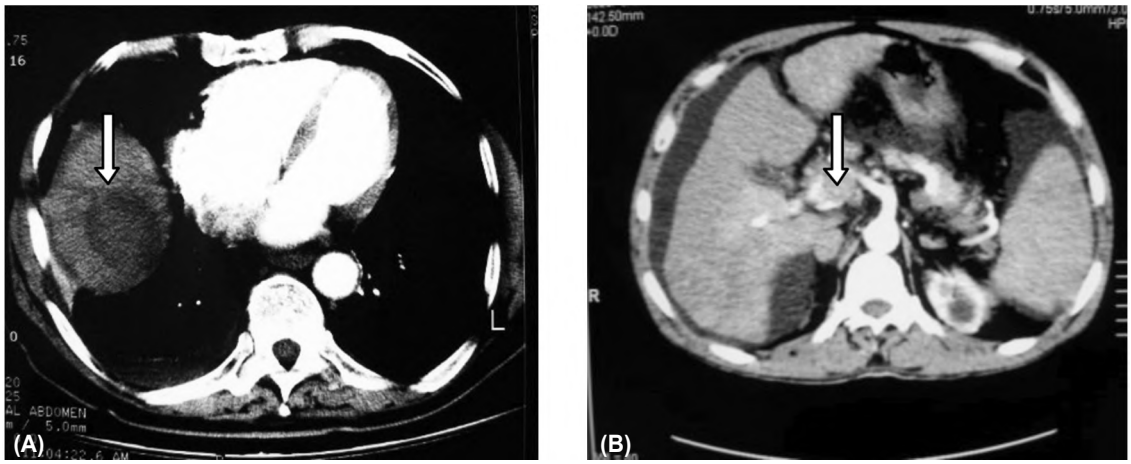

Fig. (4): A hepatocellular carcinoma in segment 8 that was treated by percutaneous radiofrequency ablation (RFA) (arrow). A, Transverse helical portal venous phase CT scan obtained 1 month after RFA. Nonenhancing filling defect (arrow) is present in main portal vein, and ascites was noted.

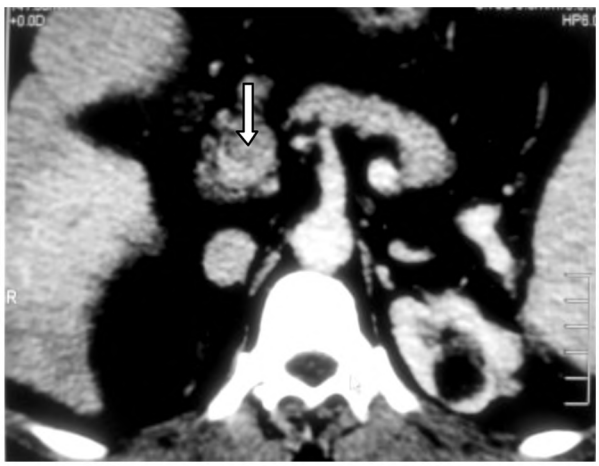

Fig. (5): Portal vein thrombosis in a 58-year-old woman with hepatocellular carcinoma in segment II. Follow-up CT scan, obtained immediately after RF ablation, shows loss of enhancement in the main portal vein (arrow).

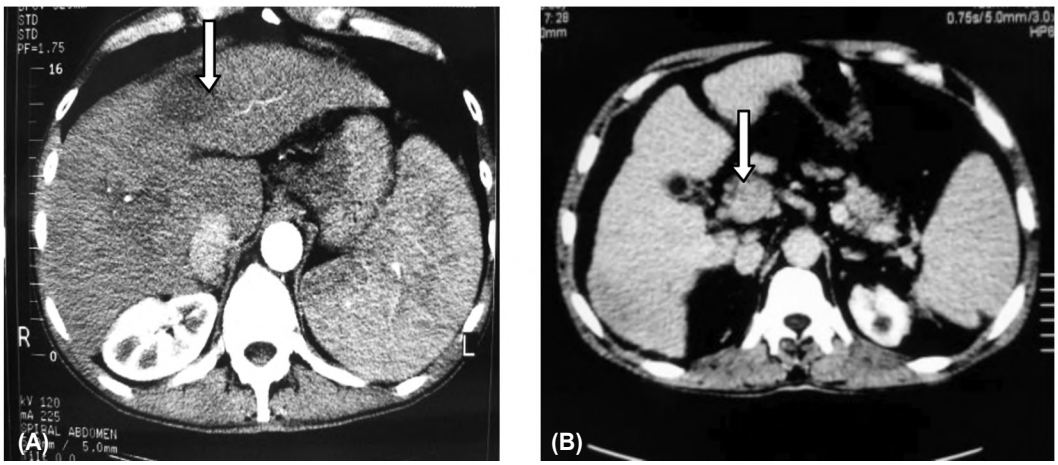

Fig. (6): Post procedural computed tomographic scan shows complete ablation of the liver tumour (arrow) (A), and subsequent portal vein thrombosis (arrow) (B).

Table (1): Preoperative background characteristics of HCC patients with and without EV who underwent RF ablation.

Variable		With EV (121)	Without EV(47)	*p*-value
Age (year)	<70	81 (66.9%)	24 (51.1%)	0.043 *
	≥70	40 (33.1%)	23 (48.9%)	
Sex	Female	30 (24.7%)	13 (27.7%)	0.421
	Male	91 (75.3%)	14 (72.3%)	
Etiology of cirrhosis	HBV	41 (33.9%)	24 (51.1%)	0.072
	HCV	61 (50.4%)	20 (42.5%)	
	Mixed (B/C)	19 (15.7%)	3 (6.4%)	
Lesion Lobe	Left lobe	33 (27.3%)	7 (14.9%)	0.065
	Right lobe	88 (72.7%)	40 (85.1%)	
Lesion Sub capsular	No	118 (97.5%)	46 (97.8)	0.814
	Yes	3 (2.5%)	1 (2.2%)	
Platelet (10 ■/L)■	Mean ± SD	(123.9±59.7)	(147.6±65)	0.025 *
	Median (Rang)	111 (5-470)	133 (54-334)	
Prothrombin Activity (%)	Mean ± SD	78.3±19.8	73.1±15.5	0.012*
	Median (Rang)	80 (7-100)	73 (7-100)	
Albumin (g/L)	Mean ± SD	39.3±4.2	39.5±7.8	0.146
	Median (Rang)	40 (28-51)	40 (3-54)	
Bilirubin (mg/dL)	Mean ± SD	21.5±13.3	16.5±11.3	0.01
	Median (Rang)	18 (3-77)	12 (3-52)	
Alfa fetoprotein (ng/mL)	Mean ± SD	184.3±499.4	37.3±64.8	0.125
	Median (Rang)	10 (2-3189)	7 (1-250)	
Lesion Size (mm)	Mean ± SD	26.9±9.6	26.6±11.9	0.263
	Median (Rang)	25 (10-50)	22 (10-70)	

*Statistically significant.

Table (2): Complication of RF ablation.

Variable	Data		*p*-value
	Without EV	With EV	
Complication:			
No	(42/47) (89.4%)	104/121 (85.95%)	0.3
Yes	(5/47) (10.6 %)	17/121 (14%)	
Ascites	1	2	0.1
Pleural effusion	2	4	0.2
Fever	2	3	0.1
Portal vein thrombosis	0	6	0.04*
Liver decompensation	0	1	0.2
Hematoma	0	1	0.2

*Statistically significant.

Table (3): Logistic regression analyses of risk factors for occurrence of complication in patients without esophageal varices after RFA (N=47).

Variable	Complication		*p*-value	Odds ratio (95 % CI)
	No (n=42)	Yes (n=5)		
Age (years):			0.674	
<70Y	21 (87.5)	3 (12.5)		
›_70Y	21 (91.3%)	2 (8.7)		
Sex:			0.023*	14.6 (1.45-148.05)
Male	33 (97.1)	1 (2.9)		
Female	9 (69.2)	4 (30.8)		
Etiology:			0.792	
HBV	20(84.3)	4 (16.7)		
HCV	20 (100)	0 (0)		
Mixed	2 (66.7)	1(33.3)		
Platelet			0.443	
Prothrombin			0.061	
Albumin			0.968	
Bilirubin			0.633	
Alfa fetoprotein			0.662	
Lesion Lobe:			0.121	
Left	5 (71.4)	2 (28.6)		
Right	37 (925.)	3 (7.5)		
Lesion Size			.908	
Lesion capsular:			.999	
No	41 (89.1)	5 (10.9)		
Yes	1 (100)	0 (0)		

*Statistically significant.

Table (4): Logistic regression analyses of risk factors for occurrence of complication in patients with esophageal varices after RFA (N=121).

Variable	Univariate			Multivariate logistic analysis	
	Complication		*p*-value		
	No (n=104)	Yes (n=17)		Odds ratio (95 % CI)	*p*-value
Age (years):			0.731		
<70Y	69 (85.2)	12 (14.8)			
›_70Y	35 (87.5%)	5 (12.5)			
Sex:			0.896		
Male	78 (85.7)	13 (14.3)			
Female	26 (86.7)	4 (13.3)			
Etiology:			0.160		
HBV	32 (78)	9 (22)			
HCV	56 (91.8)	5 (8.2)			
Mixed	16 (84.2)	3 (15.8)			
Platelet			0.03*	0.987 (0.975-998)	
Prothrombin			0.2		
Albumin			0.340		
Bilirubin			0.696		
Alfa fetoprotein			0.312		
Lesion Lobe:			0.04*		
Left	21 (63.6)	12 (36.4)			
Right	83 (94.3)	5 (5.7)			
Lesion Size			.803		
Lesion capsular:			.997	0.977 (0.965-988)	
No	101 (86.3)	17 (13.7)			
Yes	3 (100)	0 (0)			

*Statistically significant.

Table (5): Multivariate cox-regression analyses for overall survival in the patients with and without esophageal varices.

Variable	Cox-analysis (Hazards Ratio)			
	Without EV (47)		With EV (121)	
	HR (95% CI)	*p*-value	HR (95% CI)	*p*-value
Age: (<70Y ›-70Y)	1.28 (0.489-3.369)	0.613	2.38 (0.044-5.122)	0.445
Sex: (Male/Female)	0.476 (0.121-1.85)	0.284	0.663 (0.054-8.132)	0.748
Etiology: HBV/HCV/Mixed	1.15 (0.24-5.49)	0.929	3.56 (0.564-3.56)	0.998
Platelet	1.05 (.998-1.12)	0.097	1.011 (0.984-1.040	0.415
Prothrombin	1.01 (0.96-1.004)	0.977	0.972 (0.931-1.04)	0.185
Albumin	0.93 (0.84-1.004)	0.225	1.06 (0.761-1.49)	0.716
Bilirubin	0.978 (0.94-1.02)	0.282	0.937 (0.857-1.025)	0.155
Alfa fetoprotein	1.001 (1.0-1.002)	0.54	1.01 (1.00-1.03)	0.052
Lesion Lobe: (Left/Right)	0.623 (0.190-2.4)	0.435	0.039 (0.001-1.162)	0.061
Lesion Size	0.993 (0.941-1.05)	0.794	1.03 (0.921-1.51)	0.606
Lesion Capsular: (No/Yes)	1.43 (0.678-3.46)	0.988	0.003 (0.001-0.391)	0.019*

*Statistically significant.

Discussion

Radiofrequency (RF) ablation of early stage HCC is minimally invasive and highly curative [11].Past studies have established that hepatic function or tumor stage impact outcome of patients with HCC who have undergone RF ablation therapy [12].In the current study, we investigated whether or not the presence of EV determined by endoscope influence either the survival prognosis or reason for complication in early HCC patients.

The prognostic estimation of the existence of EV has been forward in few reports. Bruix et al., noticed that post surgical, cirrhotic patients with high portal pressure were at incredible chance of hepatic decompensation **[13]**. Minagawa et al., found that the survival rate was forty six in patients with EV and that the presence of EV was an independent predictor of a poor prognosis **[14]**. Notwithstanding, The European Association for the Study of the Liver in like manner suggested that portal hypertension be viewed as a contraindication for liver resection **[15]**. Kim et al., revealed that both Child-Pugh class B and EVs to be independent factors of poor prognosis in HCC patients treated with RF ablation **[16]**. On other side. Capussotti et al., demonstrated that the existence of portal hypertension should not be studied associate absolute reason to hepatic resection in these patients **[17]**. Imamura et al., demonstrated that portal hypertension did not impact postoperative complications **[18]**.

Results of our study showed that patients with EVs can tolerate RF ablation of HCC. Two factors showing significant relationships with RF ablation related complication, thrombocytopenia and left lobe location of HCC. Portal vein thrombosis was the most type of complication and subcapsular location of HCC significantly affected survival.

The frequency of treatment-related PV thrombosis after RF ablation in patients without Evs in the present study was 0%. which is lower than the frequency found in a study by Kim et al. and de Baere et al. **[19,20]**, who reported that PV thrombosis occurred in 1.08% (15/1379), and 1.7% (6/350), respectively. On other side, the frequency PV thrombosis a in patients with Evs was 4.9%.

PV thrombosis after RF ablation is caused mainly by heat damage to the endothelial cells of the PV near the ablation zone **[21]**, which in turn leads to platelet aggregation and the following development of thrombosis **[22]**.

PV thrombosis of vessels larger than 4mm after RF ablation is infrequent, provided that normal flow is maintained through these vessels **[23]**. In general, slow and stagnant portal flow in patients with portal hypertension and EVs enhance the development of thrombus. The relative reduction

in the size of the left lobe and the slow and stagnant tendency of portal flow adjacent to HCC lesions supporting the high results of complication in left lobe location **[19]**.

On other side, thrombocytopenia is a marker of portal hypertension and EV, it pertains to liver function and tumor burden. Previous studies, considered that thrombocytopenia, was independently side with expanded complications, postoperative liver insufficiency, and mortality after resection of HCC **[24]**.

In the current study, the overall survival of patients with EV after a median follow-up of 11.6 months was 77.7% in comparison to the survival rates of subjects without EV which were 66%. Our results were better than Kim et al., who reported cumulative survival rate were 56% at 3 years **[16]**.

Previous studies, suggested that the presence of EVs may have an effect on survival because of the following two mechanisms. One of the mechanisms is the relationship between the degree of portal hypertension and hepatocarcinogenesis **[25]**. The other mechanism is the contact between portal blood flow and hepatic reconstruction. As convenient inflow of portal blood into the liver is crucial for prompt hepatic reconstruction after RF ablation **[26]**.

Conclusion:

In conclusion, this current study has proven that patients with portal hypertension and EVs can tolerate RF ablation of HCC. Dealing caution as regard correction of thrombocytopenia and professionally as regard location of HCC, we can improve the outcome of RF ablation.

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تأثير دوالى المرئ على نتائج الاجتثاث بالتردد الحرارى فى مرضى سرطان الخلايا الكبدية

الهدف من الدراسة: تحدسد الفعالية للاجتثاث بالتردد الحرارى فى مرضى سرطان الخلايا الكبدية المرتبط بدوالى المرئ، وعوامل الخطر الهامة التى تؤثر على النتيجة.

المرضى والطرق: ١٢١ من ١٦٨ مريضاً يعانون من ارتفاع ضغط الدم بالوريد البابى ودوالى المرئ، وخضع للاجتثاث بالتردد الحرارى كعلاج لمرض سرطان الكبد. تم تقييم الفعالية العلاجية. تم الكشف عن تحليلات الانحدار اللوجستى لعوامل الخطر لحدوث مضاعفات وتحليل متعدد الانحدار كوكس من أجل البقاء العام.

النتائج: معدل الاجتثاث الكامل كان ٨٨.٤٪. تخثر الوريد البابى هو أكثر أنواع المضاعفات. من خلال التحليل أحادى المتغير، كان نقص الصفائح الدموية عامل خطر مستقل من المضاعفات. من خلال التحليل متعدد المتغيرات، كان موقع الورم بالفص الأيسر عامل خطر مستقل من المضاعفات وموقع الورم تحت الكبسول من العوامل النذير مستقلة من أجل البقاء.

الخلاصة: لقد أثبتت هذه الدراسة الحالية أن المرضى الذين يعانون من ارتفاع ضغط الدم البابى ودوالى المرئ يمكن يخضعوا بنجاح للاجتثاث بالتردد الحرارى كعلاج لمرض سرطان الكبد. عند توخى الحذر فيما يتعلق بتصحيح نقص الصفائح الدموية وبصورة احترافية كموقع لمرض سرطان الكبد، يمكننا تحسين نتيجة الاجتثاث بالتردد الحرارى.