Risk Factors Affecting the Outcome of Radiofrequency Ablation of Hepatic Cancer among elderly patients

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Abstract:

Background: Hepatic cancer is the third common cause of cancer worldwide, and is the leading common type of deaths due to cancer. The objective of this study was to determine the efficacy of radiofrequency ablation for hepatic cancer, and the important risk factors that affect the outcome.

Methods: We enrolled 168 patients diagnosed with a single carcinoma (diameter ≤5 cm); 121 patients presenting with esophageal varices (EV) and 47 patients without EV, who underwent radiofrequency ablation as treatment. Logistic regression analyses of risk factors for the occurrence of complications and multivariate coxregression analyses for overall survival were performed.

Results:

Complete ablation was achieved in 107 hepatic cancer (88.4%) of patients presenting with EV, and in 38 hepatic cancer (80.9%) of patients presenting without EV, left lobe lesion (P = 0.01), decreased in platelet count (P = 0.02), and decreased in prothrombin concentration (P= 0.02) are independent factors for RF ablation complication, after 24 months follow up period, the difference in survival between these two risk groups was insignificant (P = 0.097)

Conclusion: This study showed that most patients with hepatic cancer with EV can tolerate RF ablation, and four factors were recognized to affect the outcome of RF ablation and survival rate.

Keywords: Radiofrequency ablation, hepatic carcinoma, esophageal varices

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Introduction:

Hepatic cancer is the third top reason of deaths due to cancer worldwide, and the most common type of deaths due to cancer [1] . hepatitis B and hepatitis C viruses (HBV &HCV) respectively are the most commonly reported risk factors

for chronic liver diseases causing hepatic cancer. Combined they are in responsible for 85% of all hepatic cancer cases all over the world; of this percentage, about 54% are result from HBV, and 31% as a result of HCV [2, 3]. It represents more than 80% of total hepatic cancer morbidity and mortality in the developing countries [2]. Recent estimates of hepatic cancer incidence in Egypt, revealed an age-standardized incidence rate of 20.6–21.7/100,000 among men which is more than twice the incidence of hepatic cancer among men in the United States[4] . The outcome of hepatic cancer patients presenting with esophageal varices (EV) is significantly worse than that of general hepatic cancer patients. This may to be defined by more severe underlying cirrhosis and a higher frequency of advanced hepatic cancer with predominant portal vein thrombosis[5].

Surgical resection was not a viable treatment option in this group of patients. consequently appear that trans-arterial chemoembolization may offer some survival advantage to this precise organization of patients, provided that their liver capabilities had been nonetheless reasonable and the portal vein changed into patent. In a recent study, progression of hepatic cancer rather than complications of cirrhosis was the most common cause of in the long-term life loss among patients presenting with EV[6] . A history of recent variceal bleeding is often considered a contraindication for trans-arterial chemoembolization for hepatic cancer. Liver transplantation is another choice for affected patients with concurrent cirrhosis and hepatic cancer, and the lack of donors and dropout from the ready list continue to be the drawbacks of this treatment, Radiofrequency (RF) ablation treats hepatic cancer in a targeted way [7]. To our knowledge, few studies have focused on this group of patients, and have revealed that the presence of EV may change the prognosis of hepatic cancer in patients who underwent RF ablation. Thus, this study aimed to assess the efficacy of RF ablation in patients with and without EV, as well as the important risk factors that affect the outcome of radiofrequency ablation in patients with hepatic carcinoma.

Patients and Methods:

Study design and sample

This is intervention study carried out at Sohag University Hospital. The study included two categories of patients: category one those patients diagnosed hepatic cancer without esophageal varices (EV), and the second category is those diagnosed with hepatic cancer associated with esophageal varices. We enrolled 168 patients diagnosed with a single hepatic cancer (diameter ≤5 cm) and splenomegaly; 121 patients of them presented with EV and 47 patients without EV. EV was diagnosed using upper esophagogastric endoscopic examinations. Splenomegaly was diagnosed using ultrasonography (US).

Written informed consent was obtained from all the patients for RFA treatment. The treatment decision was approved after taking the advice of experienced consultants of surgeons, oncologists and gastroenterologists.

Diagnosis of esophageal varices

All patients were diagnosed with portal hypertension, based on splenomegaly [8] in association with thrombocytopenia [9] ,esophageal varices detectable on endoscopy. Esophago-gastric endoscopic examinations were not routinely performed in our study. Esophageal varices were diagnosed in 121 patients with significant upper gastrointestinal bleeding. Splenomegaly was diagnosed based on the long axis of the spleen >10 cm on computed tomography [7]. According to the guidelines of our center, RF ablation was selected for patients with Child-Pugh class A, and well-preserved liver function[10].

Diagnosis and staging of hepatocellular carcinoma

Contrast-enhanced triphasic CT and US were performed before the RF ablation session for all participants. The diagnosis of HCC was assigned using the noninvasive criteria defined by the American Association for the Study of Liver

Disease recommendations, which consisted of arterial hyper enhancement with washout seen on portal or delayed-phase images[11]

Post-operative follow-up

We designed the observation and follow up program as immediate observation for two days at the hospital to detect operative complications in which the patient exposed to abdominal ultrasound and complete blood picture. One month later the patients subjected to ultrasound and CT examinations to evaluate the procedure response. Patients with ablated hepatic cancer were subjected to a follow-up program using ultrasound and CT examinations every 3-6 months for 18 months

RF ablation techniques

All patients were under went percutaneous RFA under ultrasound guidance with general anesthesia and all RF ablation sessions were performed by the same team based on tumor size, and patient condition. The aim was to achieve complete ablation of hepatic cancer with safety margin of at least 0.5 cm around the tumor. RFA was defined as insertion of the electrode into the tumor during the same session.

Statistical analysis:

Data analysis was carried out using SPSS software program version 22. We tested our results for normality using the Shapiro test which guided us to use non parametric tests. For quantitative data we used man Mann-Whitney test for comparison, and categorical variables were compared using Chi-square ($\chi 2$) test. We assessed overall survival (OS) using the Kaplan–Meier curve and compared it with log-rank test. We used cox regression analysis to identify significant hazard risk factors (HR) for the occurrence of complications after RFA, and Statistical significance was set at $p<0.05$.

Results

Table (1): Preoperative characteristics of Hepatic cancer patients with and without EV who underwent Radio frequency ablation

variable	Without EV (47)	With EV (121)	P value
Age (year) <60 ≥60	 24 (51.1%) 23 (48.9%)	 81 (66.9%) 40 (33.1%)	**0.043***
Sex Female Male	 13 (27.7%) 14 (72.3%)	 30(24.7%) 91 (75.3%)	0.421
Cause of cirrhosis HBV HCV Other	 24(51.1%) 20 (42.5%) 3 (6.4%)	 41(33.9%) 61(50.4%) 19 (15.7%)	0.072
Lesion Lobe Left Right	 7 (14.9%) 40 (85.1%)	 33 (27.3%) 88 (72.7%)	0.065
Lesion Size (mm) Mean ±SD Median (Rang)	 26.6± 11.9 22 (10-70)	 26.9± 9.6 25 (10-50)	0.263
Lesion Sub capsular No Yes	 46 (97.8) 1 (2.2%)	 118 (97.5%) 3(2.5%)	0.814
Albumin Mean ±SD Median (Rang)	 39.5± 7.8 40 (3-54)	 39.3± 4.2 40 (28-51)	0.146
Bilirubin Mean ±SD Median (Rang)	 16.5± 11.3 12 (3-52)	 21.5± 13.3 18 (3-77)	.01
Platelet Mean ±SD Median (Rang)	 (147.6± 65) x10³/mm³ 133 (54-334) x10³/mm³	 (123.9± 59.7) x10³/mm³ 111 (5-470) x10³/mm³	**0.02***
Prothrombin concentration Mean ±SD Median (Rang)	 78.3± 19.8 80 (7-100)	 73.1± 15.5 73 (7-100)	**0.01***
Alfa fetoprotein Mean ±SD Median (Rang)	 37.3± 64.8 7 (1-250)	 184.3± 499.4 10 (2-3189)	0.125

*Statistically significant

Table (2). Complication and therapeutic response of RF ablation

	With EV	Without EV	P value
Ablation			
• Complete ablation	107 (88.4%)	38 (80.9%)	0.15
• Local tumor progression	14 (11.6%)	9 (19.1%)	
Complication			
• No	104 (85.95%)	42 (89.4%)	
• Yes	17 (14%)	5 (10.6 %)	0.3
- Major(pneumothorax/hematoma)	3(1.79%)	0 (0%)	
- Minor (fever-mild pleura effusion)	14(12.21%)	5 (10.6%)	
Mortality rate			
• Living	94 (77.7%)	31 (65.9 %)	
• Death due to liver failure	5 (4.1%)	5 (10.6 %)	0.3
• Death due to cancer	12 (9.9 %)	6 (12.8 %)	
• Death due to other cause	10 (8.3%)	5 (10.6 %)	

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)				
<60Y	21 (87.5)	3 (12.5)	0.674	4.4(0.97-12.18)
≥60Y	21 (91.3%)	2 (8.7)		
Sex				
Female	9 (69.2)	4 (30.8)	**0.02***	14.6(1.45-15.05)
Male	33 (97.1)	1(2.9)		
Causes of Cirrhosis				
HBV	20(84.3)	4 (16.7)	0.792	2.3(0.13-4.92)
HCV	20 (100)	0 (0)		0.36(0.06-2.37)
Other	2 (66.7)	1(33.3)		
Lesion Lobe				
Left	5 (71.4)	2 (28.6)	0.121	3.67(0.89-4.67)
Right	37 (925)	3 (7.5)		
Lesion Size			.908	1.2(0.13-2.76)
Lesion capsular				
No	41 (89.1)	5 (10.9)	.999	2.56(0.87-4.78)
Yes	1 (100)	0 (0)		
Albumin			0.968	0.87(0.57-2.01)
Bilirubin			0.633	0.95((0.90-1.07)
Platelet			0.443	0.98(.97-1.02)
Prothrombin			0.061	0.96(0.84-1.09)
Alfa fetoprotein			0.662	0.99(0.93-1.03)

*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		Odds ratio (95 % CI)	p value	Adjusted Odds ratio (95 % CI)	p value
	No (n= 104)	Yes (n=17)				
Age (years) <60Y ≥60Y	69 (85.2) 35 (87.5%)	12 (14.8) 5 (12.5)	0.89(0.79-1.05)	0.731		
Sex **Female** **Male**	26 (86.7) 78 (85.7)	4 (13.3) 13 (14.3)	3.7(0.88-15.63)	0.896		
Cause of cirrhosis HBV HCV Other	32 (78) 56 (91.8) 16 (84.2)	9 (22) 5 (8.2) 3 (15.8)	0.92(0.16-5.3) 0.51(0.86-3.03)	0.160		
Lesion Lobe right left	80 (90.9) 24 (72.7)	8 (9.1) 9 (27.3)	5.26(2.21-0.67)	**0.01***	3.91(1.34-11.72)	**0.01***
Lesion Size			1.4(0.87-2.76)	0.803		
Lesion capsular No Yes	101 (86.3) 3 (100)	17 (13.7) 0 (0)	0.87(0.81-3.76)	0.997		
Albumin			0.95(0.84-1.08)	0.340		
Bilirubin			0.95(0.91-1.2)	0.696		
Platelet			0.97(0.76-0.99)	**0.02***	0.95(0.78-0.97)	**0.02***
Prothrombin			0.72(0.48-0.82)	**0.0.3***	0.68(0.53-0.78)	**0.0.2***
Alfa fetoprotein			0.89(0.80-2.67)	0.312		

*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(<60Y ≥60Y)	1.28(0.489-3.369)	0.613	2.38(0.	0.445
Sex(Male/Female)	0.476(0.121-1.85)	0.284	0.663(0.054-8.132)	0.748
Causes of cirrhosis HBV/HCV/Other	1.15(0.24-5.49)	0.929	3.56(0.564-3.56);,	0.998
Lesion Lobe (Right/Left)	0.623(0.190-2.4)	0.435	1. 61(1.31-1.189)	**0.04***
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	1.3(1.02-3.04)	**0.01***
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
Platelet	1.05(.998-1.12)	0.097	1.1(1.07-2.06)	**0.02***
Prothrombin	1.01(0.96-1.004)	0.977	1.2 (1.13-3.42)	**0.03***
Alfa fetoprotein	1.001(1.0-1.002)	0.54	1.01(1.00-1.03)	0.052

*Statistically significant

The background characteristics of patients with hepatic cancer those with and without EV who underwent RF ablation are shown in (table 1). Both groups of patients were similar in terms of sex, etiology of cirrhosis, location of hepatic cancer (lobe & sub capsular), size of the hepatic cancer, and laboratory findings (albumin, bilirubin, and α-fetoprotein). The degree of thrombocytopenia (P=0.025) and prothrombin activity (P= 0.012) were more significant and worse toward the patients with esophageal varices.

For the treatment of hepatic cancer, complete ablation was achieved in 107(88.4%) of patients presenting with EV, and in 38 (80.9%) of patients

presenting without EV, Post-procedural complications occurred in 17 (14%) patients presenting with EV; 3 (1.79 %) major complications, two patients developed pneumothorax, and one patient developed large hematoma. Minor complications like fever and mild pleural effusion, were observed in 12.2% of patients with EV and in (10.6%) patients without EV. There are 18 deaths were related to hepatic cancer progression (12(9.9%) in patients with EV and 6 (12.6%) in patient without EV), 10 deaths due to liver failure 5 (4.4%) in patients with EV and 5 (10.6%) in patients without EV), and 15 were related to other causes; 10 (8.3%) in patients with EV and 5 (10.6%) in patients without EV), with no statistically significant difference (Table 2).

Univariate logistic regression analysis was performed for participants without EV, revealing that being male has higher chance of developing complications after RF (OR= 14.6 (1.45-15.05), P=0.2), for the participants who had EV, univariate logistic regression and multivariate logistic regression analysis revealed that, left lobe lesion (OR=3.91(1.34-11.72), P=0.01), decreased platelet count (OR=0.95(0.78-0.97), P= 0.02), and decreased prothrombin concentration (OR=0.68(0.53-0.78), P= 0.02) were independent factors for post RF ablation complication, (Table 2&3).

Multivariate Cox regression analysis of overall survival rate for the participants with EV differed from the participants without EV, for those without EV, no HR affecting the survival rate was identified, for the patient who had EV four factors recognized affecting the survival rate; two patient-related factors included decreased platelet count (HR = 1.1(1.07-2.06), P = 0. 02), and decreased the prothrombin concentration (HR =1.2 (1.13-3.42) P =0.03) The tumor-related factors included, absence of tumor capsule (HR =1.3(1.02-3.04) P =0.01), and the left lobe location of the lesion (HR = 1. 61(1.31-1.189), P =0.04), (Table 5). The follow-up period was 24 months. None of the patients were lost follow-up. Kaplan–Meier survival curves: Indicate the difference in survival between these two risk groups was insignificant (P = 0.097). The patients with esophageal varices group (121 patients) and patients without esophageal varices group (47 patients) survival rates were 77.7% at (95% confidence interval: 1613–1865) and 66 % at (95% confidence interval: 1501–1856), respectively. (Table 5& (Figure1)

Discussion

In our study, we found that complete ablation was achieved in (88.4%) of hepatic cancer patients presenting with EV, and in (80.9%) hepatic cancer patients presenting without EV. This therapeutic rate for ablation of hepatic cancer is similar to that reported by Long Jian-Yun et al., who noted that during the CT evaluation 2 days after RFA, there were (90.0%) patients had achieved "complete necrosis", the therapeutic effect of the RFA [12]. Also, Lee, MD and colleagues had found that a primary technical success was achieved in 96.2% (175 of 182) of the hepatic cancers , and also Wang, X.H., et al revealed that complete radiological ablation was achieved in (94.7%) of hepatic cancer patients[14].

In our study we found that Post procedural complications occurred in 17 patients (14%). This result was nearly similar to that reported by De Baère et al. who noted that (12%) of the hepatic cancer had major complications [15], but our results were greater than those reported by Lee, MD et al who explained that major complications were detected in only five patients (3.1%)[16] [13], also in results of an earlier study done by Wang et al. who recorded about 2.2% major complications in patients with HCC who underwent RF [17]. Lai,C.et al in, a series of 33 patients had hepatic cancer (2.2%) reported to have major complications rates after RFA [18]

The overall survival rate in our study identified two independent factors included factors included decreased in platelet count (HR = 1.1(1.07-2.06), P = 0. 02), and decreased prothrombin concentration (HR =1.2 (1.13-3.42) P =0.03) The tumor-related factors included, absence of tumor capsule(HR =1.3(1.02-3.04) P =0.01), and the left lobe location of the lesion (HR = 1. 61(1.31-1.189), P =0.04) this results were similar to Harada N et al, who reported that male sex, platelet count level and tumors number were predictors of worse survival [9]. Tumor size was associated with local recurrence but not with overall survival . Long Jian-Yun et al noticed that tumor size may influence the success of "one-off " RFA, also tumor located near the capsular had no influence on the success of "one-off " ablation, [12]. El-Fattah etal had reported that overall survival was associated

with prothrombin activity (P = 0.0001), albumin level (P = 0.0004) and total bilirubin (P = 0.0001) .

In this study the survival rate was 77.7%. When comparing our results with previous studies we will find that El-Fattah MA et al had reported a similar results as they noticed that the overall survival rates were: 83%, [19]. Two studies investigated the overall survival rate after RF ablation for hepatic cancer in patients presenting with portal hypertension [9, 20].The overall survival rate was 84.1% in the first study after RF ablation of 42 hepatic cancer, the second study reported that 92.6.% overall survival rate after treatment of 192 hepatic cancer. Also, Lee, MD etal reported that the estimated overall 1, 3, and 5 year survival rates after RFA are 94.4%, 84.1%, and 67.9%, respectively, [13].

Conclusion

The current study has shown that most hepatic cancer patients with EV can tolerate RFA, and that four factors were recognized to affect the outcome of RFA and survival rate; two patient-related factors included decreased platelet count and decreased prothrombin concentration. Tumor-related factors included the absence of tumor capsule and the location of the left lobe.

Abbreviations

EV: Esophageal varices
HBV: Hepatitis B Virus
HCV: Hepatitis C Virus
RFA: Radiofrequency Ablation
OS: Overall survival
OR: Odds Ratio
HR: Hazardous Ratio

Ethics approval and consent to participate

This study was approved by the Ethical Committee of the Faculty of Medicine, Sohag University. We explained all study details to the participants before signing informed consent. The reference number is not applicable

Consent for publication:

Not applicable, there no personal data in the manuscript (videos or images)

Availability of data and materials

All supporting data are available in a spreadsheet format and can be provided whenever required.

Competing interests:

None declared.

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None

Authors' contributions:

EMR wrote the manuscript. EM: performed the procedure and collected the data SAA: performed the statistical analysis and reviewed the manuscript.
All authors have read and approved the final manuscript.

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