

Results of radiofrequency ablation in the treatment of hepatocellular carcinoma in Veracruz, Mexico

Resultados de la ablación por radiofrecuencia en el tratamiento de carcinoma hepatocelular en Veracruz, México

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Palabras clave:

Carcinoma hepatocelular, ablación por radiofrecuencia, supervivencia, índice de masa corporal.

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ABSTRACT

Introduction: Hepatocellular carcinoma is the most frequent malignant primary hepatic tumor. Only 15% of patients will undergo surgical resection or transplantation, so local ablation is an alternative treatment with advantages. **Objective:** To evaluate the efficacy of radiofrequency ablation in our population. **Material and methods:** Retrospective study of patients with hepatocellular carcinoma who underwent radiofrequency ablation. Sociodemographic variables, tumor, stage (Child-Pugh, OKUDA, BCLC, CLIP, MELD and ALBI), use of sorafenib and survival were investigated. **Results:** We analyzed 16 patients (mean age 71.25 years) with concomitant pathology in 87.5%. Cirrhosis was present in 62.5% of the patients, 56.3% were in Child-Pugh A class and 6.3% in B class. 62.5% were OKUDA I, 37.5% were in BCLC stage A, 56.3% in BCLC B and 6.3% in BCLC C. 56.3% were staged as CLIP 0, MELD 8.44 ± 2.15 and ALBI -2.54 ± 0.42 . Mean tumor size was 5.81 ± 2.81 cm and sorafenib was administered in 25%. Median survival was 37.7 months, one-year survival was 58.5% and five-year survival was 23.4%. Body mass index was associated with low survival ($p = 0.031$). **Conclusion:** Our study indicates that radiofrequency ablation is used in patients with hepatocellular carcinoma in various stages and sometimes in tumors larger than 5 cm, making survival lower to that seen in other studies.

RESUMEN

Introducción: El carcinoma hepatocelular es el tumor primario hepático maligno más frecuente. Sólo 15% de los pacientes será sometido a resección quirúrgica o trasplante, por lo que la ablación local es un tratamiento alternativo con ventajas. **Objetivo:** Evaluar la eficacia de la ablación por radiofrecuencia en nuestra población. **Material y métodos:** Estudio retrospectivo de pacientes con carcinoma hepatocelular sometidos a ablación por radiofrecuencia; se investigaron variables sociodemográficas, del tumor, estadio (Child-Pugh, OKUDA, BCLC, CLIP, MELD y ALBI), uso de sorafenib y supervivencia. **Resultados:** Se analizaron 16 pacientes (edad media 71.25 años) con patología concomitante en 87.5%. El 62.5% de los pacientes padeció cirrosis, 56.3% Child-Pugh A y 6.3% B. El 62.5% fueron OKUDA I, 37.5% estadio BCLC A, 56.3% BCLC B y 6.3% BCLC C; 56.3% se estadió CLIP 0, MELD 8.44 ± 2.15 y ALBI -2.54 ± 0.42 . El tamaño tumoral fue 5.81 ± 2.81 cm y sorafenib en 25%. La supervivencia media fue 37.7 meses, supervivencia al año 58.5% y a cinco años 23.4%. El índice de masa corporal se asocia a baja supervivencia ($p = 0.031$). **Conclusión:** Nuestro estudio indica que la ablación por radiofrecuencia se usa en pacientes con carcinoma hepatocelular en estadios variados y en ocasiones en tumores mayores a 5 cm, haciendo que la supervivencia sea menor a otros estudios.

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Abbreviations:

HCC = hepatocellular carcinoma.
 RFA = radiofrequency ablation.
 MWA = microwave ablation.
 PEI = percutaneous ethanol injection.
 LSA = laser ablation.
 CRA = cryoablation.
 HIFU = high intensity focused ultrasound.
 INR = International Normalized Ratio.
 ALT = alanine aminotransferase.
 AST = aspartate aminotransferase.
 ALP = alkaline phosphatase.
 AFP = alpha fetoprotein.
 CLIP = Italian Liver Cancer Program.
 BCLC = stages of liver cancer in the Barcelona clinic.
 MELD = model for end-stage liver disease.
 ALBI = albumin-bilirubin index.
 BMI = body mass index.

INTRODUCTION

Hepatocellular carcinoma (HCC) is the most frequent primary malignant liver tumor worldwide.¹ It is the fifth most common neoplasm in men and the eighth most common in women and it represents the third leading cause of cancer-related mortality in the male population.² Treatments for HCC include liver transplantation, surgical resection, and local ablation methods. Liver transplantation is limited, given the scarcity of donors.³ Unfortunately, only 5-15% of newly diagnosed HCC patients will undergo potentially curative resection or liver transplantation. Surgical resection is not feasible if multifocal disease is present, if the hepatic functional reserve is insufficient, or if the proximity of the tumor to vascular or biliary structures precludes achieving sufficient margins.⁴ In the last 20 years, local ablation has become an important alternative treatment for smaller HCC and in cases considered surgically unresectable. Many different modalities have been proposed and accepted for ablation procedures; these include radiofrequency ablation (RFA), microwave ablation (MWA), percutaneous ethanol injection (PEI), laser ablation (LSA), cryoablation (CRA), high-intensity focused ultrasound (HIFU) and combinations of all these.³ RFA is used to treat small (< 5 cm) or recurrent primary tumors in patients with poor hepatic reserve (Child Pugh B and/or C), and non-significant coagulopathy. RFA has advantages such as being a minimally invasive method applied percutaneously,

for repeated use in recurrent hepatocellular carcinoma, and causing minimal damage to the hepatic parenchyma, and a with low rate of major complications.⁵ The aim of this study is to evaluate the efficacy of RFA in our study population.

MATERIAL AND METHODS

A retrospective study was conducted in which patients with a histopathological diagnosis of HCC undergoing RFA, with complete clinical records, during the period from January 1, 2013, to January 1, 2018, at the High Specialty Medical Unit of the *Hospital de Especialidades No. 14*, and at the *Hospital Regional de Alta Especialidad de Veracruz*, Mexico, were included, after having obtained the authorization by the Local Ethics and Research Committee.

Age, sex, body mass index (BMI), presence of concomitant disease (diabetes mellitus, arterial hypertension, viral hepatitis, and liver cirrhosis) and laboratory values at diagnosis were recorded, including hemoglobin level, platelet count, coagulation times, International Normalized Ratio (INR), and serum creatinine, alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), total bilirubin, total proteins, albumin, and alpha fetoprotein (AFP). Variables corresponding to ablation and related to the lesion (size) and the use of sorafenib were evaluated. Patients were classified according to Child-Pugh classification,⁶ the Italian Liver Cancer Program (CLIP),⁷ OKUDA scale,⁸ the Barcelona Clinic Liver Cancer Stages (BCLC),⁸ the model for end-stage liver disease (MELD)⁹ and the albumin-bilirubin index (ALBI).¹⁰ Patients with a final diagnosis other than HCC or without a complete or illegible clinical record were excluded. Survival was calculated from diagnosis until death or loss to follow-up.

Under ultrasound guide, the StarBurst SDE RFA Device (AngioDynamics, N.Y., USA), an electrode was inserted in the center of the tumor, which was designed to produce spherical ablations in small lesions with difficult access, applying a high frequency alternating current from the generator. The electrosurgical radiofrequency generator used was a 1500X

model, which supplies radiofrequency energy for partial or complete coagulation and soft tissue ablation, with a power of 250 watts combined with the saline infusion pump. The radiofrequency waves were administered for an average time of 10 minutes, and, after a pause, the procedure was repeated to ensure necrosis.

Statistical analysis: Mean, standard deviation and range were used to describe continuous variables, and frequencies and percentages for categorical variables. Survival was calculated using the Kaplan-Meier test and the Log-Rank test (Mantel-Cox) to compare survival between groups. The estimated mean survival was recorded in months. ROC curve was performed to determine the area under the curve and the cut-off points with sensitivity and specificity to predict those values that influence survival. Data were analyzed using the SPSS 25 software (SPSS, 2016, Chicago, USA). A p-value < 0.05 was considered statistically significant.

RESULTS

Sixteen patients were analyzed, of whom 10 (62.5%) were women and six (37.5%) men with a mean age of 71.25 ± 5.8 years (59-80 years), and a mean BMI of 25.54 ± 4.22 kg/m² (17.8-33.7). Seven (43.8%) had type 2 diabetes mellitus, four (25%) arterial hypertension, and

six (37.6%) chronic viral hepatitis; of the latter, five (31.3%) were carriers of hepatitis C and one (6.3%) of hepatitis B. Ten patients (62.5%) had liver cirrhosis. Laboratory values are shown in [Table 1](#). Based on the ablation approach, 12 (75%) were open, two (12.5%) laparoscopic and two (12.5%) percutaneous. The mean tumor lesion size was 5.81 ± 2.81 cm (3-13), of which 10 (62.5%) had a lesion smaller than 5 cm and six (37.5%) had a lesion larger than 5 cm. Nine patients (56.3%) were classified as Child-Pugh A and one (6.3%) a Child-Pugh B class. [Table 2](#) shows the staging of patients according to OKUDA, BCLC, CLIP, MELD and ALBI. Four patients (25%) received sorafenib treatment and 12 (75%) did not. Complications associated with RFA occurred in three cases (18.75%) including two (12.5%) with transient liver failure and one (6.25%) with pneumonia. The mean estimated survival (Kaplan-Meier) was 37.7 ± 10.2 months (95% CI, 17.68-57.84) and the estimated median survival was 24 months. Actuarial survival of all patients at 1 year was 58.5% and at 5 years was 23.4%.

Factors associated with survival. Deceased patients had a lower BMI (23.3 ± 3.5 kg/m²) compared to living patients (27.7 ± 3.7 kg/m²) ($p = 0.031$ by Student's t test). None of the other variables recorded had a significant difference in patient survival as shown in [Table 3](#). ROC curve

Table 1: Laboratory results at the time of diagnosis of hepatocellular carcinoma.

Parameter	
Hemoglobin g/dl	12.04 ± 1.4 [10.8-14.3]
Platelets mm ³ 10x ⁹	126.22 ± 58.97 [61.0-236.0]
Prothrombin time	13.47 ± 2.32 [10-18.90]
International Normalized Ratio	1.12 ± 14 [0.95-1.45]
Creatinine mg/dl	0.99 ± 0.22 [0.70-1.50]
ALT IU/l	45.88 ± 15.89 [31-78]
AST IU/l	46.88 ± 9.15 [29-60]
Alkaline phosphatase UI/l	163.71 ± 52.81 [114-266]
Total bilirubin mg/dl	0.83 ± 3.00 [0.26-1.40]
Total protein mg/dl	13.50 ± 2.34 [10-18.90]
Albumin g/dl	3.86 ± 41.00 [2.80-4.30]
Alpha fetoprotein	4,026.71 ± 14,132.07 [2.50-56,838.84]
Model for end-stage liver disease	8.44 ± 2.15 [6-13]
Albumin-to-bilirubin ratio	-2.54 ± 0.42 [-3.14 to -1.51]

Table 2: Staging of patients submitted to radiofrequency.

Stadium	n (%)
OKUDA	
I	10 (62.5)
II	6 (37.5)
BCLC	
A	6 (37.5)
B	9 (56.3)
C	1 (6.3)
CLIP	
0	9 (56.3)
1	5 (31.3)
2	2 (12.5)
MELD	
< 10	11 (68.75)
> 10	5 (31.25)
ALBI	
Grade 1	9 (56.3)
Grade 2	7 (43.8)

OKUDA I: none positive, II: one or two positive, ALBI grade 1: ≤ -2.60 , grade 2: -2.60 to ≤ -1.39 . BCLC = liver cancer in Barcelona clinic, CLIP = Italian liver cancer program, MELD = model for end-stage liver disease, ALBI = albumin-bilirubin index.

analysis of BMI was performed, finding an area under the curve of 0.79 (95%, CI 0.56-1.0) ($p = 0.046$) with a cutoff point of 22.06 (sensitivity 100%, specificity 38%). However, there was no difference in survival estimated by the Kaplan-Meier method (Log-Rank) when applying the cutoff point < 22.06 kg/m² with a mean of 16.0 ± 10.53 months (0.0-36.6) and > 22.06 kg/m² with a mean of 47.4 ± 12.2 months (23.5-71.3). In this case, the p-value was 0.20.

DISCUSSION

The results of our study indicate that patients who underwent RFA have lower survival at one and five years, compared to other publications that applied the same treatment. However, we found that almost 40% of the lesions were larger than 5 cm and most of the patients were at more advanced stages than those recommended by the BCLC for RFA. There

are studies with superior survival to our results when patients present lesions smaller than 5 cm. Lencioni and collaborators¹¹ evaluated cirrhotic patients (Child-Pugh A and/or B class), early stage of HCC (BCLC A, lesions smaller than 5 cm) submitted to RFA, obtaining a survival of 97% at one year and 41% at five years, with a median of 49 months.¹¹ Kim and his group,¹² in patients who underwent RFA, obtained 59.7% survival at five years, with significant predictors for lower survival being the patient age, Child-Pugh in class B and the presence of extrahepatic recurrence. In turn, Lee and associates¹³ evaluated 162 patients with more than three tumors with a maximum diameter of 5 cm, finding a five-year survival of 67.9%, where the most significant predictors of lower survival rate were Child-Pugh class B, elevated AFP levels and the presence of portal hypertension. Even though these studies recorded higher survival rates than ours, there are others in which survival is like ours with lesions larger than 5 cm and patients in intermediate stages of BCLC. Among these studies are that of Nouse and collaborators¹⁴ which included 91 patients in intermediate stages of BCLC (B1, B2 and B3) and in which survival of 73.8% at three years and 57.3% at five years was achieved. Also, the study of Dai W and associates,¹⁴ which involved 63 patients who underwent RFA with a mean lesion size of 6.0 cm (5.2-8.0), obtaining a survival rate at one, three and five years of 93.3, 70.5 and 20.9%, respectively, with a median survival of 39.8 months. And finally, the study of Yin X and associates¹⁵ that analyzed 49 cases with tumor size between 3-7 cm and survival rate at one year of 75.8% and at five years of 15.4%. The use of RFA in intermediate stages and lesions larger than 5 cm with five-year survival rates like ours (around 20%) may justify the use of this resource in our population, which has been reported since 2006.¹⁶

There are studies that support that BMI has a significant impact on the prognosis of patients with HCC. Qinggan Li and associates¹⁷ analyzed 379 patients, where those with a BMI less than 23 kg/m² had a survival of 353.9 days (316.9-391.0) and with a BMI greater than 23 kg/m² they found a survival rate of 571.8 days (532.3-611.4). Likewise, Xiyu Liu and

associates¹⁸ evaluated 136 patients, obtaining higher survival rates in patients with a BMI less than 25 kg/m² of 95% at one year and 16% at five years than in those with BMI greater than 25 kg/m² ($p = 0.048$). Our study found an estimated median survival of 1,410 days (47 months) in patients with BMI greater than 22.06 kg/m²; furthermore, these patients did achieve survival records greater than five years. Unfortunately, we were unable to confirm this association as a risk factor by statistical analysis (ROC curve/Cox regression), possibly because of our sample size. Our study points out that

the use of sorafenib after RFA influences a longer survival rate than in those patients who did not receive it. This agrees with the series by Feng et al¹⁹ that included 64 patients with single therapy (RFA) and 64 with combined therapy (RFA + sorafenib), finding a median survival rate of 118.6 weeks and 161.8 weeks, respectively; and with the study by Quanyou and associates²⁰ that analyzed 50 patients with single therapy and 40 with combined therapy, finding a tumor-free survival rate of 8.4 and 12.3 months, respectively, with a median follow-up of 35 months.

Table 3: Survival estimates by the Kaplan-Meier method.

Variable	Mean \pm SD, months	95% CI	Survival at one year (%)	Five-year survival (%)	p-value
Body mass index	16.00 \pm 10.53	0-36.65	34.17	NR	0.2
< 22.06	47.43 \pm 12.2	23.51-71.35	64.70	48.55	
> 22.06					
Type 2 diabetes mellitus					
No	44.50 \pm 15.66	13.79-75.2	66.45	44.40	0.73
Yes	23.31 \pm 5.7	12.13-34.49	53.33	NR	
Arterial hypertension					
No	41.94 \pm 13.7	15.08-68.80	83.30	27.78	0.28
Yes	14.31 \pm 3.22	8-20.63	56.14	NR	
Viral hepatitis					
No	37.93 \pm 13.00	12.43-63.42	66.66	35.56	0.91
Yes	26.16 \pm 7.69	11.08-41.24	66.67	NR	
Liver cirrhosis					
No	15.66 \pm 4.04	7.74-23.59	67.50	33.75	0.82
Yes	33.83 \pm 10.07	14.09-53.57	66.10	NR	
Lesion size					
< 5 cm	21.75 \pm 6.08	9.83-33.66	53.57	NR	0.25
> 5 cm	51.42 \pm 14.03	23.92-78.92	71.43	53.57	
OKUDA					
I	40.42 \pm 11.82	17.25-63.59	72.92	27.34	0.43
II	14.16 \pm 4.05	6.21-22.12	50.00	NR	
Alpha fetoprotein					
< 200	34.37 \pm 11.2	12.40-56.34	60.61	22.73	0.68
> 200	14.25 \pm 4.95	4.53-23.96	50.00	NR	
Sorafenib					
No	20.00 \pm 3.68	12.78-27.21	66.45	NR	0.93
Yes	38.04 \pm 12.45	13.63-62.44	58.74	29.37	

OKUDA I no positive criteria, II one or two positive, SD = standard deviation, NR = not recorded.

There is very little information on the use of RFA in patients with HCC in our country. Mondragón-Sánchez and collaborators²¹ published the use of RFA in a variety of liver tumors, the majority being HCC (n = 18) with a mean lesion size of 5.5 cm, a one-year survival rate of around 20% and an estimated mean of 18 months. Subsequently, Ladrón de Guevara and associates²² published on the use of RFA in two patients with HCC with a one-year survival of 40 months and an estimated mean survival of eight months. Recently, Cisneros Garza and associates²³ reported the use of RFA in 13 patients, six in stage A, seven in stage B and one in stage C class without specifically reporting their survival. The results of our study evidenced a better survival rate both in the estimated mean time and the percentage of survival at one year without being able to compare it at five years, since it was not reported. For this reason we assume that this is the Mexican study of RFA for HCC with the highest mean follow-up published to date.

CONCLUSIONS

RFA in Veracruz, Mexico, is used in patients with HCC at various stages and in tumor lesions of various dimensions, with mixed results, depending on the characteristics to be studied. The results of RFA in Veracruz, Mexico, may be the largest follow-up of this therapeutic modality in our country. Given the size of the sample, it is not possible to establish risk factors that may significantly influence this therapy.

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