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ORIGINAL ARTICLE / ОРИГИНАЛНИ РАД

Radiofrequency ablation for hepatocellular carcinoma – analysis of the clinical outcome

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SUMMARY

Introduction/Objective Radiofrequency ablation (RFA) is a minimally invasive treatment modality for primary and metastatic liver tumors. It can be performed percutaneously or as a laparoscopic or open surgical procedure under ultrasound or computerized tomography guidance.
The objective of the study was to evaluate the clinical outcome of the initial 16 patients with hepatocellular carcinoma (HCC) managed by percutaneous RFA at a tertiary institution and to assess the efficacy of this procedure in the management of selected patients with HCC.

Method From June 2011 until December 2013, 16 patients with early-stage HCC were managed by percutaneous radiofrequency ablation at the Clinic for Digestive Surgery, Clinical Center of Serbia, Belgrade. All the patients were treated by the same team composed of an interventional radiologist and a liver surgeon. We analyzed the clinical outcome and the biologic effect of this treatment by comparing the pre- and post-treatment levels of alpha-fetoprotein (AFP).

Results Post-treatment values of liver transaminase levels returned to the pre-treatment values from Day 3. Post-treatment hospital stay was two days. Post-procedural complications included mild pain in all patients, skin necrosis at the site of the electrode puncture in five patients, and transient hepatic decompensation in one patient. In all the patients the AFP level correlated with the findings of liver imaging (ultrasound and/or magnetic resonance imaging with liver-specific contrast agent) indicating viability of the treated tumor.

Conclusion RFA is a feasible and effective procedure providing favorable clinical outcome in patients with early-stage HCC.

Keywords: radiofrequency ablation; hepatocellular carcinoma; biologic effect; percutaneous approach

INTRODUCTION

Radiofrequency ablation (RFA) is a minimally invasive treatment modality for primary and metastatic liver tumors. It can be performed as percutaneous or as laparoscopic or open surgical procedure under ultrasound (US) or computerized tomography (CT) guidance. When performed percutaneously, patients can be managed using local analgosedation avoiding general anesthesia. Radiofrequency ablation is an alternative treatment option to hepatic resection for patients with small, primary liver tumors [1, 2, 3]. It is a safe procedure achieving survival as long as 10 years in the latest reports and it is considered a curative treatment modality [4]. For selected patients with early-stage hepatocellular carcinoma (HCC), RFA can be used as a first-line treatment option. However, the results of the treatment are dependent on operator experience [5].

The advantages of RF ablation are the following: a) it is an effective treatment for primary and metastatic liver tumors in selected patients who are unsuitable for surgical resection; b) treatment-related serious complications are infrequent and discomfort is minimal; c) the procedure may be used repeatedly to treat recurrent liver tumors; d) the percutaneous approach is minimally invasive, produces few complications, and may be applied in ambulatory settings; e) it is a relatively quick procedure associated with quick recovery so chemotherapy may be resumed almost immediately if required; f) it is less expensive than other treatment options; g) no surgical incision is needed.

The clinical outcome of patients treated with RFA can be assessed using laboratory analysis and imaging modalities. Several studies confirmed that alpha-fetoprotein (AFP) measurements indicate the necrotic effect of locoregional thermal ablation [6, 7, 8], while other studies confirmed the biologic role of AFP in a neoplastic growth [9]. AFP is a fetal-specific glycoprotein normally produced primarily by the fetal liver. Normally, AFP levels decline rapidly after birth, reaching undetectable levels (< 10 ng/ml) within several months after birth [6, 7, 8]. Increased AFP levels indicate the presence of cancer, most commonly liver cancer, ovarian cancer, or germ cell tumor of the testicles. However, not every liver, ovarian, or testicular cancer will produce significant quantities of AFP [8, 9].

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In the present study we analyzed the clinical outcome of the first 16 patients with early-stage HCC treated by RFA at a tertiary institution and we assessed the efficacy of this procedure using post-procedural imaging and measuring pre- and post-treatment levels of AFP.

The study objective was to evaluate the clinical outcome of the first 16 patients with an early-stage HCC managed by a percutaneous radiofrequency ablation and to assess the efficacy of this procedure using post-procedural imaging and serum levels of AFP.

METHODS

From June 2011 until December 2013, 16 patients with early-stage HCC were managed by percutaneous radiofrequency ablation at the Clinic for Digestive Surgery, Clinical Center of Serbia, Belgrade. During the same period, five additional patients were managed by the same procedure for a solitary metastatic tumor in the liver as they were not eligible for open surgery due to their co-morbidities. All the patients were managed by the same team composed of an interventional radiologist and a liver surgeon. According to revised version of the Barcelona Clinic Liver Cancer system endorsed by the American and European Association for Study of the Liver, the patients diagnosed at an early stage are defined as follows [10]: "very early" with a single node less than 2 cm in size, in Child–Pugh A class, with no symptoms and no change in performance status; and "early", when single node, smaller than 5 cm, or up to 3 nodes < 3 cm each, in Child–Pugh A-B class, with no symptoms and no change in performance status.

All the patients included in this study met the following criteria: (a) no extrahepatic spread of a disease; (b) liver tumor less than 5 cm in diameter; (c) adequate functional liver parenchyma; (d) no obstructive jaundice; and (e) no simultaneous operative procedures on other organs.

The preoperative workup of the patients included: (a) accurate liver imaging utilizing multi-detector CT or magnetic resonance imaging (MRI); (b) the assessment of hepatic functional reserve; (c) AFP measurement.

In all the patients, biochemical liver function tests were monitored before and on the first day after the RFA. Static biochemical liver function tests were used to assess hepatic functional reserve since all the patients had liver cirrhosis. Liver abscess, subphrenic abscess, bile leakage, sepsis, chest involvement, and post-procedural bleeding were considered procedure-related complications. Follow-up protocol included laboratory analysis, AFP measurement, and US examination one, three, and nine months after the RFA and laboratory analysis, AFP measurement and MRI with a liver-specific contrast agent (Primovist®, Bayer AG, Leverkusen, Germany), six and 12 months following RFA. After the first year, the patients were followed on six months bases using abdominal MRI and AFP level. The follow-up period for patients included in the study ranged 24–42 months.

In all the patients, RFA was performed using a Cool-tip® (Valleylab, Tyco) water-cooled, single, RF tumor ablation electrode, with a 30 mm non-insulated tip, connected to a 480 kHz 200 watt generator (Valleylab Cool-tip® RF System). RF energy was applied by gradually increasing the output to maximum power, achieving thermal ablation of tumor tissue. Under US guidance, the electrode was repositioned until the complete tumor ablation was performed.

Table 1. Patient and tumor characteristics

Variable	RFA, n = 16 pts
Sex (M/F)	11/5
Age	60.5 (47–79)
Cirrhosis etiology	
Hepatitis B	5
Hepatitis C	9
Co-infection hepatitis B and C	1
Hepatitis B and ethylic	1
Liver function status	
Child–Pugh A	13
Child–Pugh B	3
Tumor number	
1	15
2	1
Tumor size (mm)	25.5 (21–40)
Tumor localization	
Segment II/III	2
Segment IVB	1
Segment V	4
Segment VI	5
Segment VII	3
Segment VIII	2

RFA – radiofrequency ablation

Four patients were treated under local analgosedation and 12 under general anesthesia. Other patients' data are presented in Table 1.

All the patients had liver cirrhosis of viral origin with Child status A or B. Child B patients had either lower albumin level (30–35 g/l), moderate ascites responsive to diuretics treatment and/or increased bilirubin level (Child–Pugh B8). However, only Child B patients with sufficient remnant liver volume and compensated liver function were considered for RFA. All patients managed by percutaneous RFA in this study had compensated liver function. All the patients included in this study were not candidates for liver resection due to their co-morbidites, liver function, or due to tumor localization that would require major liver resection with insufficient liver remnant.

The patients were diagnosed either by liver biopsy (histological confirmation of HCC and cirrhosis during the previous surgery / liver resection or by ultrasound-guided biopsy performed in another institution) or by typical radiological findings of HCC (arterial enhancement and wash-out on portal phase) on CT or MRI imaging in combination with an increased level of AFP (normal range up to 10 ng/ml).

Informed consent was obtained from all the patients before RFA.

All data were prospectively collected and entered into a computerized data base. All the data are expressed as median with the range.

RFA procedure

All RFA treatments were performed under a standard protocol using the Cool-tip® RF needle with a 3 cm exposed tip. The ablation was performed with a curative intent, aiming to achieve a margin of 1 cm. After completing the procedure a safe margin of 1cm was assessed by measuring the ablated zone. In all the patients the ablated zone was at least 1cm larger than the size of the tumor. The patients were reviewed by a multidisciplinary team before the approach of RFA was decided (intercostal in 10 and subcostal in six patients). The percutaneous ablation was performed by ultrasound guidance under local analgosedation (four patients) or under general anesthesia (12 patients). The ablation was performed using the manual mode with continuous monitoring of the impedance, RF current, and the temperature (Figures 1–3). The non-insulated tip of the electrode was continuously perfused with cold saline via internal channels inside the needle throughout the ablation to maintain the tip temperature below 15°C, preventing charring around the electrode tip.

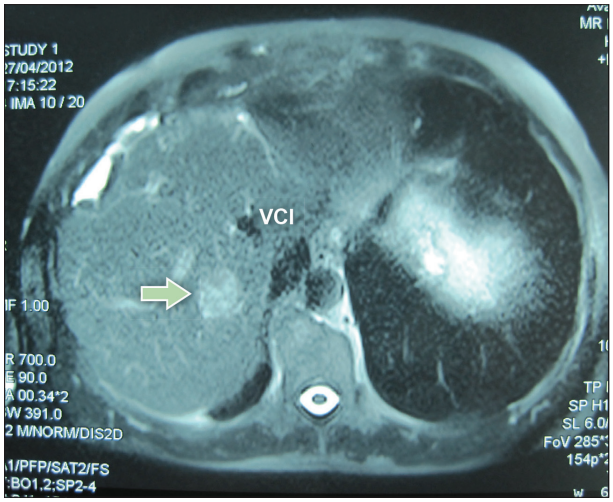

Figure 1. Pretreatment abdominal MRI demonstrating a tumor in liver segment VIII

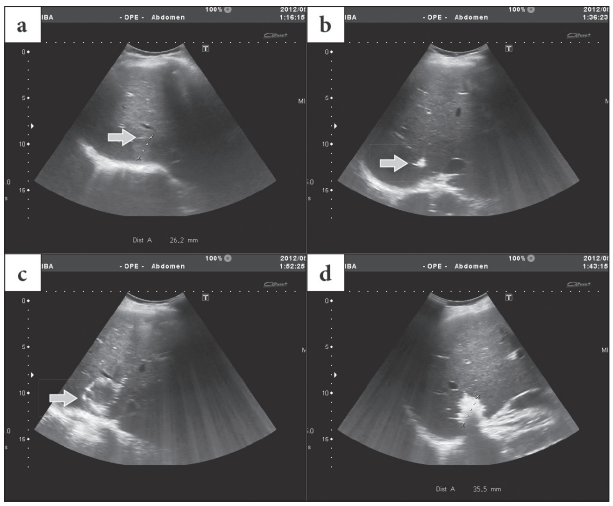

Figure 2. US-guided radiofrequency ablation procedure for hepatocellular carcinoma in liver segment VIII; a) US tumor measurement, localization and positioning of the needle; b) start of ablation; c) progress of ablation; d) end of procedure, ablation zone

RESULTS

Sixteen patients with early-stage HCC in cirrhotic livers underwent curative-intent RFA. Peri-procedural transfusion was not required in any patient.

The pretreatment and post-treatment profile of liver enzymes (bilirubin, aspartate aminotransferase (AST), alanine aminotransferase (ALT), and prothrombin time (PT)) and hemoglobin and platelets is presented in Table 2. The post-treatment values of AST and ALT returned to pretreatment values from Day 3.

The post-treatment hospital stay was two days [2–8]. Post-procedural complications included mild pain in 14 patients, skin necrosis at the site of the needle puncture in five patients, and transit hepatic decompensation in one patient (Table 3).

During the follow-up period, two patients were managed by transarterial chemoembolization (using a mixture of Lipiodol and cisplatin) as the tumor size exceeded 3 cm (42 mm) or due to tumor recurrence. Mortality was not recorded during the follow-up period.

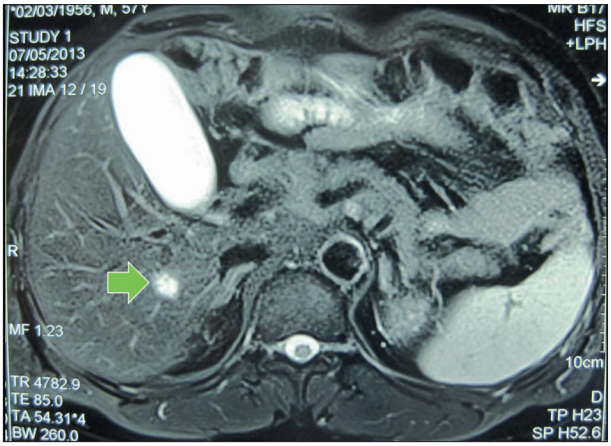

Figure 3. Post-treatment abdominal MRI using a liver-specific contrast agent demonstrating complete tumor ablation

Table 2. Pre- and post-treatment profile of liver enzymes and hemoglobin/platelets

Variable	Before RFA	After RFA
Bilirubin (μmol/L)	24.1 (8.6–92.3)	28.1 (18.2–80.4)
AST (U/L)	56.5 (34–227)	226.5 (87–529)
ALT (U/L)	46.5 (22–137)	147.5 (33–411)
Prothrombin time	147.5 (33–411)	14 (11.3–24.3)
Hemoglobin (g/L)	129 (107–158)	116.5 (97–156)
Platelets (10^9/L)	113 (40–178)	89.25 (40–162)

RFA – radiofrequency ablation; AST – aspartate aminotransferase; ALT – alanine aminotransferase

Table 3. Post-procedural complications

Variable	n (%)
Pain (mild)	14 (87)
Nausea	0
Vomiting	0
Fever	0
Skin necrosis	5 (31)
Transit liver decompensation	1 (6)

Table 4. Pre- and post-procedural measurement of AFP; correlation with liver imaging

Patient	Pre- AFP	AFP 1M	AFP 6M	MR/Primovist
1	21.9	6.5	5.9	Complete ablation
2	26	10.6	7.7	Complete ablation
3	1,703	24.1	11.1	Complete ablation
4	147.2	5.7	7.2	Complete ablation
5	145.1	366.6	11.8	Complete ablation
6	4,848.8	22.9	14.3	Complete ablation
7	1,216.7	55.1	11.4	Complete ablation
8	13.4	8.7	8.8	Complete ablation
9	1,746	33.1	21,748	Incomplete/recurrence
10	30.1	4.7	5.2	Complete ablation
11	12.5	5.5	4.9	Complete ablation
12	14,964	8,232	/	/
13	13.2	15.6	9.9	Complete ablation
14	40.5	12.8	10.1	Complete ablation
15	13.8	10.6	11.2	Complete ablation
16	409.4	55.1	14.8	Complete ablation

AFP – alfa-fetoprotein; 1M – one month after the treatment; 6M – six months after the treatment

In one patient, one month following RFA, alpha-fetoprotein level had increased from pretreatment levels of 145.1 ng/ml to 366.6 ng/ml. An abdominal US examination confirmed incomplete tumor ablation and the patient was re-treated using the same procedure. At the six-month follow-up AFP measured 11.8 ng/ml. This result correlated with the finding of complete ablation verified by the abdominal MRI using liver-specific contrast agent.

In one patient at the six-month follow-up, AFP level significantly increased to more than 20,000 ng/ml. This result correlated with the finding of recurrent tumor adjacent to the ablation zone verified on abdominal MRI using a liver-specific contrast agent. The tumor recurrence was managed by liver resection and intraoperative exploration has demonstrated new encapsulated tumor adjacent to the ablation zone. At the time of surgery, the patient liver function improved to Child A status.

In the two presented patients with recurrent tumor, the AFP level correlated with the findings of liver imaging (abdominal US and/or MRI with liver-specific contrast agent) indicating viability of the treated tumor (Table 4).

DISCUSSION

Radiofrequency ablation for small HCC demonstrated a survival benefit comparing to percutaneous ethanol injection as indicated by randomized controlled trials and meta-analyses and systemic reviews [11, 12]. For many years, these results established RFA as a standardized local thermal ablation technique for treating small liver tumors.

Novel ablation thermal and non-thermal techniques, including microwave ablation and irreversible electroporation, have some potential to overcome the limitations of RFA but further clinical investigations are required [13].

The complete ablation rate of RFA for liver tumors was found to vary from 50% to 95% in different reports [14]. In the present study, a complete ablation was achieved in 14 out of 16 patients (87%) after the initial RFA and in 94% of patients after the repeated procedure in one patient having a recurrent tumor. Only one patient required surgical treatment due to recurrent tumor adjacent to the ablation zone.

Significantly different results of RFA are usually attributed to the differences in the electrode design, generators, and application techniques. The importance of operator experience was reported by Poon et al. [5]. They report that complete ablation was achieved in 84% of the first 50 patients managed by RFA, while in the following 50 patients 100% ablation rate was achieved. In the present study, the success rate for initial 16 patients with small HCC managed by RFA was 87%. In the same study by Poon at al., close collaboration between the surgeons and radiologists was suggested in order to shorten the learning curve and plan the best strategy for ablation. In the present study, pretreatment analysis, deciding on the RFA approach, RFA procedure, and post-treatment follow-up were performed in a multidisciplinary team approach by an interventional radiologist and a liver surgeon.

Complication rates following RFA of liver tumors range 0–27% [15, 16]. Reported RFA treatment-related complications include pneumothorax; symptomatic pleural effusion; bleeding from the needle track or into the treated tumor; biliary fistula; biliary stricture; biloma; abscess in the treated tumor; skin burn; cholecystitis; thermal injury to adjacent structures including the diaphragm, stomach, duodenum, and transverse colon; liver failure; segmental hepatic infarction; paralysis of the hemidiaphragm; arterial-portal venous fistula; systemic hemolysis; tumor lysis syndrome; myoglobinemia or myoglobinuria; transient acute renal failure; and prolonged post treatment pain for lesions near the hepatic capsule [15]. According to Livraghi et al. [17] and Mulier et al. [18], the complication rates are higher after open or laparoscopic RFA compared to the percutaneous approach. A possible explanation is that more difficult cases are treated by open or laparoscopic approach and due to surgery-related complications.

In the present study, during the follow-up period, early and late post procedure complications did not occur. This is mainly due to proper patient selection and due to collaboration between the interventional radiologist and liver surgeon, which is rarely reported in literature [5].

In the present study, two out of the first 16 patients had HCC in seg. VIII (and one more patient with metastatic liver tumor not included in this series) not eligible for open surgery. In the reviewed literature this tumor localization is considered difficult for percutaneous approach or associated with serious complications [19, 20]. The two patients had uneventful post-procedural course and demonstrated no complications in the follow-up period.

The most common complication in the present study was skin burns at the site of the electrode puncture detected in the first five patients treated by RFA. In the reviewed literature, the majority of reported skin burns after percutaneous radiofrequency ablation occur along the edge of the grounding pads or during the tract ablation phase [14, 21, 22]. In the present study, skin burns resulted

from an excessive tract ablation to prevent tract seeding; however, in the following 11 patients, this complication did not occur.

The most important result of the study is related to the comparison of alpha-fetoprotein measurements and liver imaging indicating the biologic effect of the applied treatment.

There is a consensus in the literature that AFP regulates neoplastic growth through the presence of an alpha-fetoprotein cell surface receptor that undergoes internalization to the cell interior growth [9].

In HCC there is a strong correlation between AFP values, tumor dimensions, and microvascular invasion, as predictors of HCC recurrence [23]. According to reports from the literature, AFP is a surrogate of tumoral activity and vascular invasiveness. AFP-mRNA concentration is used as a marker of HCC cell dissemination into the circulation, which is an additional proof of this correlation [24, 25].

In the present study, the AFP level increased from pretreatment level of 145.1 ng/ml to 366.6 ng/ml one month after the RFA in one out of 16 patients. Abdominal US examination confirmed incomplete tumor ablation and the patient was re-treated using the same procedure. At the six-month follow-up, AFP measured 11.8 ng/ml, correlating with the finding of complete ablation on abdominal MRI using liver-specific contrast agent.

In another patient at the six-month follow-up, the AFP level significantly increased to more than 20,000 ng/ml, correlating with the finding of recurrent tumor adjacent to the ablation zone on abdominal MRI using liver-specific contrast agent. The tumor recurrence was managed by liver resection. The pathology finding demonstrated a new encapsulated tumor adjacent to the ablation site.

In other patients, normal AFP values correlated with complete tumor ablation verified by liver imaging techniques. Therefore, in all the patients the AFP level correlated with the findings of liver imaging (abdominal US and/or MRI using liver-specific contrast agent) indicating viability of the treated tumor.

New tumor markers are continuously discovered and investigated, but they are still far from the routine clinical practice.

The present study confirmed the need for the development of a new predictive model combining radiological and biological features based on biological markers as already indicated by Giovanni B et al. [26].

CONCLUSION

Percutaneous RFA is a first-line treatment option for carefully selected patients with small-sized/early-stage HCC in a cirrhotic liver when performed at a tertiary institution by a multidisciplinary team. The procedure is associated with a minimal morbidity offering curative treatment for this difficult category of patients.

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Радиофреквентна аблација хепатоцелуларног карцинома – анализа клиничког исхода

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САЖЕТАК

Увод/Циљ Радиофреквентна аблација (РФА) минимално је инвазиван начин лечења примарних и метастатских тумора јетре. Може се извести перкутано, лапароскопски или отворено хируршки, под контролом ултразвука или компјутеризоване томографије.

Циљ овог рада је да прикаже клинички исход лечења првих 16 болесника са хепатоцелуларним карциномом (ХЦК), третираних перкутаном РФА у терцијалној установи и да процени ефикасност ове процедуре у лечењу селектованих болесника са ХЦК.

Метод У периоду од јуна 2011. до децембра 2013. године 16 болесника са раним ХЦК третирани су перкутаном РФА. Анализирали смо клинички исход и биолошки ефекат лечења поредећи ниво алфа-фетопротеина (АФП) пре и после третмана.

Резултати Ниво трансаминаза после интервенције враћао се на вредности пре третмана од трећег дана. Боравак у болници је трајао два дана (2–8). Постпроцедуралне компликације су биле: благи бол код свих болесника, некроза коже на месту пункције електродом код пет болесника и пролазна декомпензација јетре код једног. Код свих болесника ниво АФП је корелирао са налазом на јетри (ултразвук и/или магнетна резонанца са специфичним контрастом за јетру), указујући на вијабилност третираног тумора.

Закључак РФА је изводљива и ефикасна процедура која обезбеђује повољан клинички исход код болесника са раним ХЦК.

Кључне речи: радиофреквентна аблација; хепатоцелуларни карцином; биолошки ефекат; перкутани приступ