Research Article

Evaluation of Open Surgical Resection versus Percutaneous Radiofrequency Ablation for Single Malignant Hepatic Focal Lesion

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Abstract
Purpose: This study assesses and evaluates the treatment outcome of open hepatic resection versus percutaneous Radiofrequency Ablation regarding their feasibility, radicality and availability of both techniques , Morbidity and local tumor recurrence, will be also evaluated. **Methods:** A prospective study of ٣٠ patients their ages ranged from ٤٠to ٧٠ years with single malignant hepatic focal lesion mainly hepatocellular carcinoma (HCC) with lesion size from ٢-٧cm were enrolled in this prospective randomized double blind study ١٤ patients treated by open surgical resection and ١٦ patients treated by percutaneous radiofrequency ablation (RF) . only patients with Child class A or early B are selected.
Results: Regarding to frequency of recurrence we found that two patients (١٢.٥٪) in Radiofrequency group after one year of follow up and no recurrence detected in resection group. **Conclusion:** over all recurrence and survival in favor of surgical resection due to more reliable local tumor control. The advantage of surgery was more evident for HCC>٣ cm. Therefore, resection depending on surgical treatment feasibility and on impairment degree of hepatic parenchyma should be considered the treatment of choice.
Keywords: Hepatic focal lesion – Resection- Radiofrequency ablation

Introduction
Hepatocellular carcinoma (HCC) is the fifth most common solid cancers in the world, with an estimated ٥٠٠,٠٠٠ deaths per year [١]. Different therapies are available in hands such as surgical resection and liver transplantation which are considered the first line of treatment in patients fulfilling Milan criteria. Other minimally invasive therapies like radiofrequency ablation and Tran catheter arterial chemoembolization (TACE) are preserved for in-operable patients or any contra, indications for surgery [٢]. Hepatic resection has been accepted as the treatment of choice for HCC in many centers. Unfortunately, the associated underlying liver cirrhosis limits the extent and number of the surgical procedures due to increased risk of postoperative liver failure due to late status of most patients at time of presentations. So, many nonsurgical minimally invasive ablative methods have been developed, such as cryoablation, percutaneous ethanol injection (PEI), acetic acid injection, radiofrequency ablation (RFA), microwave coagulation, and Tran catheter arterial chemoembolization (TACE) [٣]. However, favorable survival outcomes have been reported for patients with small HCCs following radiofrequency ablation (RFA). Unfortunately there is no enough randomized controlled trials to compare between hepatic and RFA as primary treatment options in HCC [٤]. Several recent studies have reported that the operative mortality rates of patients resected for HCC vary widely according to the baseline Model for End-stage Liver Disease. Based on the fact that RFA is a repeatable technique that can be done many times and also based upon the multicenteric nature of the disease with possibility of newly developed foci in the follow up radiological studies. RFA is assumed to be superior to surgery in terms of cost and the length of hospital stay as well as post operative morbidity and mortality so in our study we will conduct a study to compare the treatment

outcome in the two treatment modalities in our institute.[٥]

Patients and methods

After obtaining approval of the local ethics committee in El-Minia university hospital and written informed consent from patients prior to entry into the study, ٣٠ patients (according to sample size)of either sex , aged between ٤٠-٧٠ years old with single lesion hepatocellular carcinoma were enrolled in this prospective randomized double blind study . This study carried out at surgery department and invasive radiology unit at Minia university hospital.

Inclusion criteria:

(١) Age range was ٤٠-٧٠ years old
(٢) Patient with HCC only selected
(٣) Child-Pugh class A and early B will be included.
(٤) Only patients with a single hepatic malignant lesion (ranging from ٢-٥cm diameter).
(٥) No previous treatment for single hepatic malignant lesion
(٦) No evidence of extra hepatic extension of the disease (celiac and Para aortic lymph nodes, portal vein invasion)

Exclusion criteria:

(١) Child-Pugh late B & C
(٢) Patients with single hepatic malignant lesion above ٧ cm diameters
(٣) Multiple lesions in both hepatic lobes
(٤) Portal vein thrombosis
(٥) Nodal or distant metastasis

All Patients underwent the following:

١- Complete history taking and clinical examination:

A- personal history (age, alcohol consumption, addiction)
B- Presenting symptom (mainly: abdominal pain and symptoms of chronic liver diseases (chronic hepatitis, liver cirrhosis)
C- History of any preceding disease or previous operations and history of bilharzias
D- Abdominal examinations (to detect any mass, organomegally, sign of cirrhosis, or ascities)

٢- Laboratory investigations:

A) Complete blood count (hemoglobin, RBCs, Platelets count).
B) Liver function tests (Albumin, bilirubin, ALT, AST).
C) Prothrombin time (PT) and concentration (PC).
D) Renal function (urea, creatinine)
E) Alpha fetoprotein (AFP)

٣- Radiological evaluation:

(a) Abdominal ultrasonography
(b) Triphasic computed tomography

Patient and tumor characteristic: Age, Gender Child Pugh class A and early B, Alpha feto protein level**,** Associated co-morbidity (DM, hypertension)**,** Sites of tumor, Diameter of tumor

Group A (resection group)

Pre operative diagnosis by Triphasic CT, Elevation of alpha-fetoprotein level greater than ٤٠٠ ng/mL; Liver function and prothrombin time and concentration to asses' child classes' patient with child class A (٥-٦) points and early B.

Radiofrequency ablation (RFA)

Pre procedure diagnosis by Triphasic CT, Eleva-tion of alpha-fetoprotein level greater than ٤٠٠ ng/mL; Liver function and prothrombin time and concentration to asses' child classes' patient with child class A (٥-٦) points and early B.

Procedure: Radiofrequency (RF) ablation was performed at the interventional unit, the patient lie supine either in ultrasound or CT suite according to lesion location, the skin was dripped by disinfectant and covered by sterile linin, local anesthetic infiltration was injected from the skin deeply to the liver capsule, then introduction of RF electrode either guided by US, CT or both of them according the location of the lesion. For percutaneous RF ablation, we used a commercially available system with a ٢٢٠-٢٤٠ V computer-assist RF generator (RF ٣٠٠ Boston Scientific, USA) and multitined inverterted umbrella electrode from Le Veen.

Evaluation of the following in each group:

(a) Outcome by radiological assessment
(b) Length of hospital stay.
(c) Short and long term complications.
(d) Morbidity and mortality

All patients are followed up as regard:
(a) Liver function at ١, ٣, ٧ days postoperative resection group
(b) A-fetoprotein (AFP) level.
(c) MDCT evaluation postoperative, three and six months after each treatment modality.
(d) US assessment every ٣ months.
(e) HCC recurrence is either residual viable tumor at the treated site (unclear surgical margins, incomplete RFA treatment) or at a distant site from the primary tumor (at different hepatic segments)

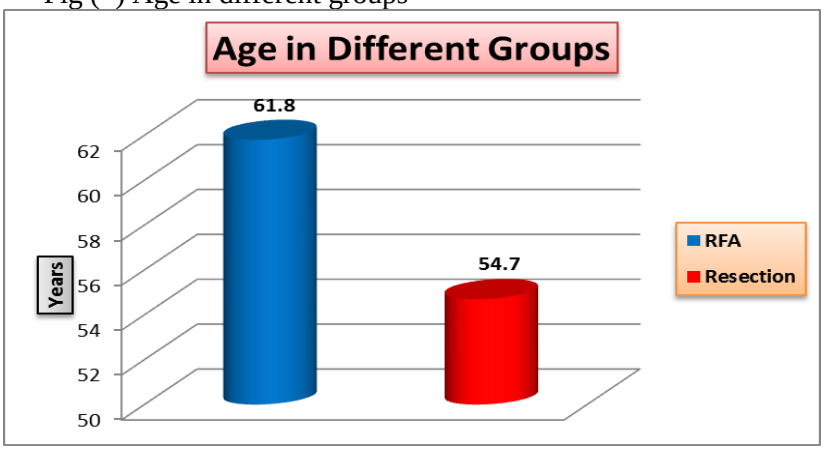
Results

As regard demographic data The age of all patient range from ٤٠ to ٧٠. The ages in RF group are older than resection group. (٦١.٨ ± ٤.٥) mean and SD in RF to (٥٤.٧ ± ٧.٧) in resection group. Sex distribution in resection group was ١٠ (٧١.٤٪) male and ٤ (٢٨.٦٪) female .in other group RF was ١١ (٦٨.٨٪) male and ٥ (٣١.٢٪) female as shown in table (١) and figure (١)

Table (١): Sex and mean of age in both group.

Variables	RFA (n=١٦)	Resection (n=١٤)	P value
Age	٦١.٨ ± ٤.٥	٥٤.٧±٧.٧	٠.٠٠٦*
Sex: **Male.** **Female.**	 ١١ (٦٨.٨٪) ٥ (٣١.٢٪)	 ١٠ (٧١.٤٪) ٤ (٢٨.٦٪)	٠.٨٧٣

Fig (١) Age in different groups



Preoperative Imaging Data

All hepatic focal lesion detected by Triphasic Computed Tomography scan (CT scan).
As detected by imaging studies the location of hepatic focal lesion (HCC) include the right lobe in ١٣ patients (٤٣.٣٪), left lobe in ١٧ patients (٥٦.٧٪) as shown in table (٢) and figure (٢)

Table (٢): location of lesions as detected by Triphasic CT scan

Location of lesion (HCC)	No. (Total=٣٠)	Percent
Right lobe	١٣	٤٣.٣٪
Left lobe	١٧	٥٦.٧٪

HCC= hepatocellular carcinoma

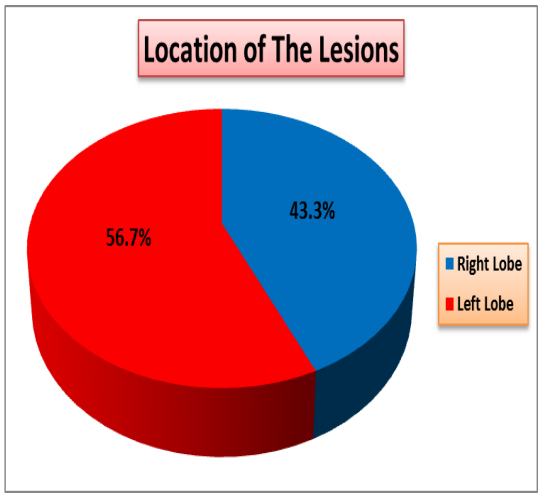


Fig. (٢): location of the lesion in each hepatic lobe

Tumor size: Tumor size differ in two group .the tumor size in resection group (٥.٣ ± ٠.٩) are larger than that of RF group (٣.٣ ± ٠.٨) that mean RF not used in lesion more than ٥cm, where resection is the treatment of choice. As shown in table (٣)

Table (٣): Difference in tumor size in two studied groups.

variable	Resection (n=١٤)	RFA (n=١٦)	P value
Tumor size	٥.٣ ± ٠.٩	٣.٣ ± ٠.٨	< ٠.٠٠١*

Child class of studied patients show that patient with early child B class underwent RF more than resection as shown in table (٤) figure (٣)

Table (٤): child class in each studied groups.

Child class:	RFA (n=١٦)	Resection (n=١٤)	P value
Child class: A:	١٠ (٦٢.٥٪)	١٣ (٩٢.٩٪)	٠.٠٨٦
early B:	٦ (٣٧.٥٪)	١ (٧.١٪)	

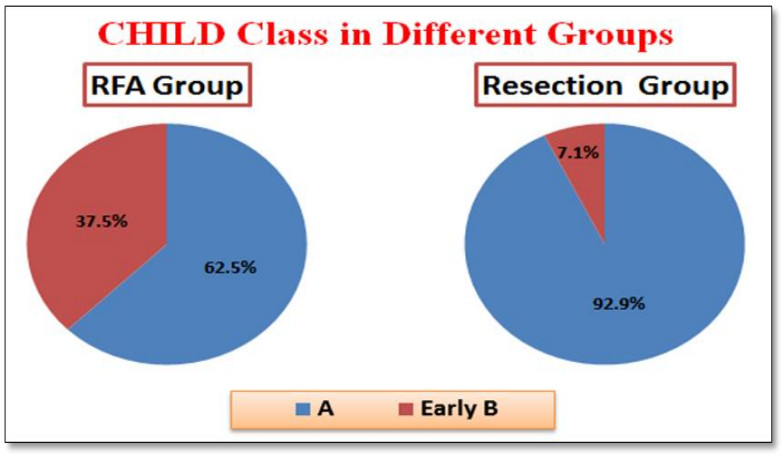


Fig. (٣): child class in each studied groups.

Perioperative data:
There was difference in blood loss in studied groups ٢ patient in RF group but ١٤ patients in resection group, as regard also transfusion amount differ and PC also as shown in table (٥)

Table (٥): show difference in PC, blood loss and blood transfusion in studied groups.

Variables	RFA (n=١٦)	Resection (n=١٤	P value
PC	٦٥.١ ± ٤.٨	٦٤.٩ ± ٤.٨	٠.٩١١
Blood loss	٢ (١٢.٥٪)	١٤ (١٠٠٪)	< ٠.٠٠١*
Amount of Blood transfusion	٥٠٠ ± ٠	٨٢٨.٦ ± ٤٦٨.١	٠.٢٤٤
Operative time (min)	٥٠.٣± ٢٥.٦	٩٧.١ ± ١٩.٨	٠.٠٠٥

RFA = radiofrequency ablation *=significant

Hospital stay:
Hospital stays in resection group are more than RF group the mean length of hospital stay in resection group is ٨.٢٥ day and in RF group is ٦.٧٥ day .as shown in table (٦)

Table (٦): Mean of hospital stay

Studied groups	Mean length of hospital stay (day)
Resection group	٨.٢٥
RF group	٦.٧٥

Complication of radiofrequency
In RFA group six patients (٣٧.٥٪) developed complication ٢ patient (١٢.٥٪) developed subcapsular hematoma and managed conservatively and one patient (٦.٢٥٪) developed intraperitoneal hemorrhage and required transfusion of one unit of blood , another patient (٦.٢٥٪) developed biloma managed conservatively without interference, and other two patient (١٢.٥٪) one of them developed pleural effusion and the other developed arterio – venous shunt of them required surgical management. As shown in table (٧)

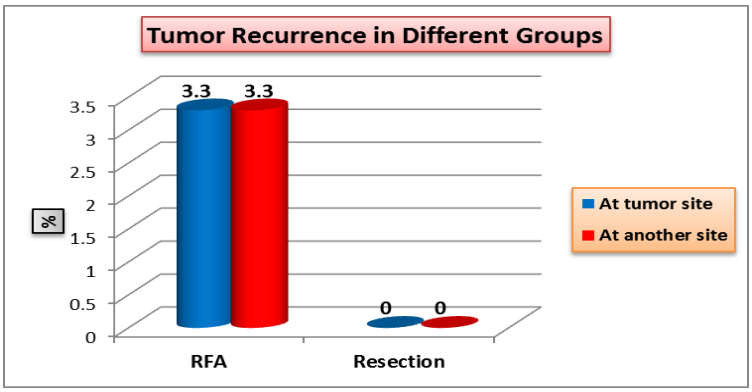
Table (٧): frequency of complication in RF group

RF group (Total No=١٦)	Frequency	Percentage
Subcapsular hematoma	٢	١٢.٥٪
Biloma	١	٦.٢٥٪
A-V shunt	١	٦.٢٥٪
Pleural effusion	١	٦.٢٥٪
Intraperitoneal bleeding	١	٦.٢٥٪

Late complication (recurrence)
Recurrence detected in two patients (١٢.٥%) in RF group after one year of follow up by Triphasic CT scan, one patients developed recurrence at same site and another patient developed recurrence at distant liver site .no recurrence detected in resection group. As shown in table (٨) figure (٤)

Table (٨): Frequency of recurrence in studied groups.

Variable	Recurrence at tumor site	Recurrence at another site	P value
In RF group (n=١٦)	١(٦.٢٥٪)	١(٦.٢٥٪)	٠.٣١٥
In resection group (n=١٤)	٠	٠	



Discussion

Hepatocellular carcinoma (HCC) is a major health problem worldwide, with an estimated incidence ranging between ٥٠٠,٠٠٠ and ١,٠٠٠,٠٠٠ new cases annually. It is the fifth most common cancer in the world, and the third most common cause of cancer related death. (Lau et al., ٢٠٠٨) Each treatment modality for HCC can be considered to have one of three goals: cure, local control and bridge to transplantation, and palliation. For years, partial hepatectomy and liver transplantation have been considered as the main curative treatments. Various locoregional therapies are used for patients who are not candidates for surgical cure because of severity of liver disease or advanced stage of HCC (Lai et al., ٢٠١١). In the past ٢ decades, local ablative therapies, including percutaneous ethanol injection (PEI), microwave coagulative therapy (MCT) and radiofrequency ablation (RFA), have emerged to be a safe and effective treatment in patients with small HCC confined to the liver, especially when the tumors are unresectable due to poor general condition or because of compromised liver function. The application of local ablative therapy has a number of potential advantages in high-risk patients with HCC. The procedure is relatively safe and well tolerated and its complication rates in most series have been low[٤] .recently, there has been a drastic shift of usage from PEI/MCT to RFA. Available evidence from adequate quality controlled studies support the superiority of RFA versus PEI/MCT, in terms of better survival and local control of the disease, for the treatment of patients with relatively preserved liver function and early-stage non-surgical HCC.[٧]

The current study done on thirty patients with single hepatic focal lesion (HCC) Patients are divided into two groups Group A (١٤) patients were subjected to open surgical resection. Group B (١٦) patients were subjected to percutaneous Radiofrequency ablation (RFA). This number of case smaller than study done by Jong et al., ٢٠١٤.[٨] Were ١٣٣ patients with single HCC Liver resection (n = ٦٦) and RFA (n = ٦٧). Also smaller than study done by Eric et al., ٢٠١٣ [٩].١١١ patients were included. ٨٠ underwent surgical resection, and ٣١ underwent

percutaneous radiofrequency ablation. Small numbers of cases in present study due to short duration of study an limited number of cases in our locality.

In the present study the age of patients in two groups are ranges from ٤٠- ٧٠ years old. this range some what resemble study done by Qinghua et al., ٢٠١٤[١٠] were range from ٤٠-٦٨ years old .also in the present study The age of RFA group are older than resection group (٦١.٨ ± ٤.٥) mean and SD in RF to (٥٤.٧ ± ٧.٧) in resection group. This result like study done by Amilcare et al., ٢٠١٣[١١] were (٦٥.٧± ٤.٣) mean and SD in RF to (٦٤.٨± ٤.٧) in resection group and also like study done by Chung ٢٠١٣[١٢] were (٦٣.١ ± ١٢.٨) mean and SD in RF to (٦٠.٨± ٩.٩). This variation in age between RF group and resection groups because with increased age co morbidity and risk of surgery increased so chance for RF is better. In present study diagnosis of HCC depending on radiological finding characteristic for HCC on Triphasic CT hypervascularization in the arterial phase with washout in the portal venous or delayed phases and elevated level of alpha feto protein more than ٤٠٠ ng/ml. mean and SD for resection group for alpha feto protein was ٣٥٩.٢ ± ١٨٠.٨ where mean and SD for RF group was ٢٩٦.٤ ± ١٨٠.٩. Pathological diagnosis by fine needle biopsy was not done. Jong et al., ٢٠١٤[٨] diagnosis based on elevated serum α-fetoprotein (AFP) (≥ ٤٠٠ ng/mL) with radiologic findings, or at least two coincidental radiologic findings compatible with HCC and pathologic confirmation. Also Eric et al., ٢٠١٣[٩] HCC was diagnosed by at least ٢ radiologic imaging showing characteristic features of HCC; or ١ radiologic imaging showing characteristic features of HCC associated with alpha-fetoprotein (AFP)>٤٠٠ ng/mL; or cytologic/ histologic evidence. So cytologic /histologic evidence in diagnosis of HCC not necessary required.

In present study our data show Tumor size differ in two group .the tumor size in resection group (٥.٣ ± ٠.٩cm) are larger than that of RF group (٣.٣ ± ٠.٨) cm with (P value< ٠.٠٠١) .that mean RF not used in lesion more than ٥cm , where resection is the treatment of choice. Eun et al., ٢٠١٤[١٣] data also show that mean diameter of HCC were ٣.٠±١.٠ cm and ٢.٣±١.٠ cm in resection group and RF group respectively and diameter of RF group were smaller than those of the resection group with P value (<٠.٠٠١). Jong et al., ٢٠١٤[٨] Tumor size are smaller than ٣cm but RF group also have smaller diameter with mean ١.٨(١.٠-٢.٩) cm than resection group ٢.١(٠.٨-٣.٠) cm with P value (٠.٠٣٥).

In present study RF group had significant shorter procedure time, blood loss and blood transfusion than resection group with mean and SD for procedure time , blood transfusion and blood loss for resection group, ٩٧.١ ± ١٩.٨ min, ٨٢٨.٦ ± ٤٦٨.١mL and ٥٣٥.٧ ± ٢٥٩.٨ respectively. And for RF group, ٥٠.٣± ٢٥.٦ min, ٥٠٠ ± ٠ respectively. In study done by Eric et al., ٢٠١٣[٩] similar result also show that RFA group had significantly shorter procedure time (mean, ٦٧.٩ vs. ١٧٧.٩ min) and less blood loss than resection group (mean, ٢٩.٦ vs. ٥١١.٥ ml).also Lei et al., ٢٠١٤[١٤] result show that the average operation time in resection group was ٤.٦±١.٣ hours, which was significantly increased compared with RF group ٢.٨±٢.٥ hours in addition, mean intraoperative blood loss in resection group was significantly increased compared with RF group (٣٢٢ ml Versus ١٠٥ ml) and also transfusion required in ١٢ cases in resection versus ٢ cases in RF group. In this study, recurrence was found after RFA, as two patients (١٢.٥%) in the RFA group developed tumor recurrence, one patients developed recurrence at same site and another patient developed recurrence at distant liver site whereas none developed it in the resection group. This may be a result of the safety margin of RFA being narrower than that of resection. In resection removes the entire lesion containing the primary tumor and surrounding healthy tissue and the clearance of tumors and any potential sites of microscopic disease will be more complete in these patients. Recurrences after RFA may be attributed to insufficient ablation of the primary tumor and/or the presence of tumor venous invasion in the adjacent regions of the liver. Many study also proved the increased percentage of recurrence with radiofrequency as in study by Eric et al., ٢٠١٣[٩] result show increased recurrence of tumor in RF group than resection group where In RFA group, tumor recurred in ٢٧ patients (٥١.٦٪) (Local recurrence, n = ٢٣), distant metastasis, n = ٤). Among the ٢٣ patients with local recurrence, HCC recurrence developed at

the site of the RFA in ٩ and at a different intrahepatic site in ١٤ of these Patients. While in resection group, tumor recurred in ١٣ patients (٢١.٣٪) (Local recurrence, n =١١; distant metastasis, n = ٢). Among the ١٣ patients with local recurrence, HCC recurrence developed at the site of the treated tumor in ٣ and at a different intrahepatic site in ١٠ of these patients. Another study by Gang et al., ٢٠١٢[١٥] show that recurrence rate at one, three and five years were significantly higher in RF group than in resection group p value (٠.٠٠٢). Lei et al., ٢٠١٤[١٤] reported significant difference in recurrence or metastasis in HCC where in ١٥٦ patient treated with RF ٧٠ patients developed recurrence and metastasis ٤٥ patients with only liver recurrence and ٢٥ patients with other organ metastasis while in ١٣٣ patients treated with resection only ٣٠ patients developed recurrence and metastasis ١٨ patients with only liver recurrence and ١٢ patients with other organ metastasis. Also Abu-Hilal et al., ٢٠١٠[١٦] reported that in resection group the local recurrence at the site of resection was documented in ٤٪ of patients, while in RF group local recurrence at the RF site was seen in ٣٠٪ of patients. Yanming et al., ٢٠١٠[١٧] reported also increased incidence of local recurrence in RF group than resection group where local recurrence was ١٩.٤ % in RF group to ٤.٠٪ in resection group. So as regard incidence of recurrence of HCC surgical resection is treatment of choice especially in lesion >٣cm.

This study has some limitations, this study is a single center study and its findings needed to confirmed and sample size is small.

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