Review Article

Complications after percutaneous ablation of liver tumors: a systematic review

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Background: Although ablation therapy has been accepted as a promising and safe technique for treatment of unrespectable hepatic tumors, investigation of its complications has been limited. A physician who performs ablation treatment of hepatic malignancies should be aware of the broad spectrum of complications. Proper management is possible only if the physician Performing ablation understands the broad spectrum of complications encountered after ablation.

Objectives: To systematically review the complications after different ablation modalities: Radiofrequency ablation (RFA), microwave ablation (MWA) and Nano knife for the treatment of liver tumors and analyze possible risk factors that precipitate these complications.

Search methods: We performed electronic searches in the following databases: MEDLINE, EMBASE and COCHARNE. Current trials were identified through the Internet (from January 1, 2000 to January 1, 2014). We included only studies who specific mentioned complications after liver ablation therapy (RFA/MWA/Nano knife).

Main results: A total of 2,588 publications were identified, after detailed examination only 32 publications were included in the review. The included studies involved 15,744 participants. According to the type of technique, 13,044 and 2,700 patients were included for RFA and MWA. Analysis showed a pooled mortality of 0.15% for RFA, and 0.23% for MWA.

Conclusions: This systematic review gathers information from controlled clinical trials and observational studies which are vulnerable to different types of bias, never the less RFA and MWA can be considered safe techniques for the treatment of liver tumors.

Keywords: Liver tumors; liver metastases; percutaneous ablation; systematic review

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Introduction

Hepatocellular carcinoma (HCC) and colorectal liver metastases (CLM) are the two most common malignant liver tumors. Hepatic resection (HR) is the only curative option, but only 15-20% of patients with liver metastases from CRC (CRLMs) are suitable for surgical standard treatment (1). For the HCC group, less than 30% of patients with HCC are eligible for surgery, mainly because of the multiplicity of the lesions that often occurs in a background of chronic liver disease, bad liver function, and deteriorating general condition (2,3).

Several alternative treatments to control and potentially cure have been developed for use in patients with malignant liver tumors, whether primary or metastatic. Interventional therapies, such as percutaneous ethanol injection (PEI), radiofrequency ablation (RFA), microwave ablation (MWA) and Nano knife has been developed for treating malignant

liver tumors.

RFA has gained wide acceptance by showing superior anticancer effects with low complications and mortality rate. Recently other emerging techniques such as MWA have attracted interest in clinical practice (4). However, these procedures will always entail some risks. Information regarding mortality and complications is absolutely essential for every intervention to permit an accurate assessment of the risks and benefits (5).

One of the greatest persistent problems in hepatic ablation has been the inability to establish quality standards in ablation complications, success, local recurrence after ablation, and nonablation hepatic recurrence. Reports from the literature are heterogeneous because of the study design, sample size, different technical approaches, and number of centers reporting complications and non-uniform terms as well as different parameters to calculate the rate of complications (6-9).

Major complications were defined as any symptom that developed after ablation and persisted for more than 1 week, or those that delayed hospital discharge, threatened the patient's life, or led to substantial morbidity and disability (10). Major complication: included death, hemorrhage, RFA needle-track seeding, intra hepatic arterial pseudo aneurysm, RFA lesion abscess, perforation of gastrointestinal viscus, liver failure, biloma, biliary stricture, portal vein thrombosis, and hemothorax or pneumothorax requiring drainage, and minor complications including pain, fever, and asymptomatic pleural effusion.

Our goal was to bring the most updated literature regarding current used techniques ("what we really do"). The use of PEI has become less favorable in the face of new modalities such MWA and Nano knife, hence we decided to remove this technique from this review.

Ablation can be done either percutaneous or by surgery, in order to minimize bias related to surgery we decided to include only papers with percutaneous technique.

Materials and methods

Inclusion criteria

Randomized controlled trials (RCTs) and nonrandomized comparative studies assessing HCC or CRLM treated with RFA, MWA or Nano knife treatment were considered for review. Only patients aged over 18 were included. In order to exclude small studies, we only considered studies analyzing more than 50 patients for at least one technique.

Search strategy

A literature search was conducted on PubMed and EMBASE to identify clinical series of RFA, MWA and Nano knife procedures for liver tumours published between January 2000 and January 2014. Letters to the editors, supplements, review articles and case reports were excluded. The titles and abstracts of all potentially relevant trials were screened by one reviewer (LE). The full text articles of potentially relevant studies were obtained. Based on the full text article, another reviewer (HA) independently determined whether the study meets the inclusion/exclusion criteria.

Data collection

Information extracted from each study included: the number of patients, age and Child-Pugh score. The type of study were categorized as prospective, retrospective, observational or randomized trial and the type of intervention included RFA/MWA, the tumor according to type (HCC or metastasis). We extracted the data type for outcome measure using number of deaths, major complications and the description of the type of percutaneous ablative technique used.

Assessment of complications

In this study complications were reported in accordance with the guidelines recommended by the Working Group on Image-Guided Tumor Ablation (10).

The definition of major complication is an event that leads to substantial morbidity and disability, increasing the level of care, or results in hospital admission or substantially lengthened hospital stay (SIR classifications C-E) (*Table 1*). This includes any case in which a blood transfusion or interventional drainage procedure is required. All other complications are considered minor. It is important to stress that several complications, such as pneumothorax or tumor seeding, can be either a major or minor complications.

Results

The search on Medline and EMBASE databases provided a total of 2,588 citations (*Figure 1*). After screening title and abstract, 2,461 were discarded. The full text of the remaining 127 citations was examined in more detail, where 95 studies did not meet the inclusion criteria as described.

Table 1 Procedure-related complication classification
Category I
No therapy, no consequence or adverse sequelae
Category II
Requires unplanned increase in level of care to a nominal degree, minimal consequence or adverse sequelae
Category III
Requires unplanned increase in level of care to intermediate degree, intermediate adverse sequelae, includes overnight admission for observation only and minor hospitalization
Category IV
Requires unplanned increase in level of care to major degree, major adverse sequelae, prolonged hospitalization (>48 h)
Category V
Death directly or indirectly related to procedure
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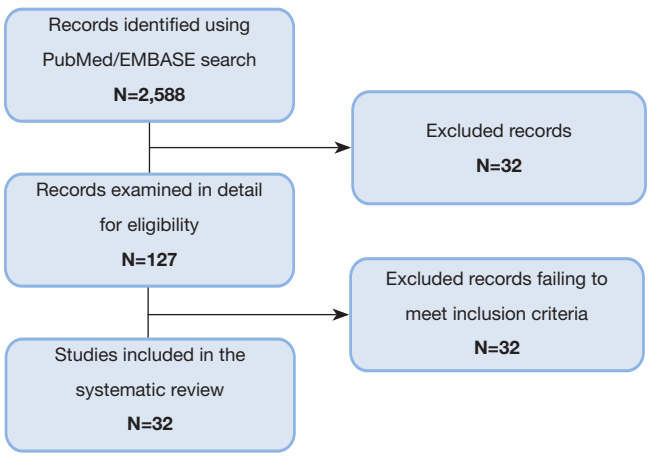

Figure 1 Study flow diagram.

Finally 32 publications were included in the review.

Characteristics

Study design, participants and interventions

Of the 32 studies selected for the review, one was randomized trials and 31 were observational studies (*Table 2*). All the reports were published after 2000 (n=32). There were 29 studies using RFA only and 2 using MWA only. One observational study evaluated RFA versus MWA.

The included studies involved 15,744 participants. According to the type of technique, 13,044 and 2,700 patients were included for RFA and MWA respectively. The average age of patients ranged from 24 to 89 years. Mean tumor size treated ranged from 1.8 to 5.0 cm. In 16 studies, mortality and complications were primary outcomes.

Specific outcomes

Death and adverse events were assessed as secondary outcomes in 16 studies. Mean follow-up after treatment ranged from 10 to 137 months. For all percutaneous ablative techniques analyzed, mortality ranged from 0% to 0.88% and the pooled proportion was 0.16% (95% CI, 0.10-0.24%) by the random effects model. Individual analysis showed a pooled mortality of 0.15% for RFA, and 0.23% for MWA.

Major complication rates were 4.1% and 4.6% for RFA and MWA respectively.

The most frequent major complication was hemorrhage intraperitoneal, subcapsular, pleural, biliary and retroperitoneal hemorrhage requiring blood transfusion (*Table 3*). Meanwhile the minor complication rates were 5.9% and 5.7% for RFA and MWA. There was no statistically significant difference in the mortality rates, major complications, and minor complications between the RFA and MWA groups (P>0.05).

Discussion

Ablation techniques have gained wide acceptance as a safe alternative to surgery in the management of early HCC and metastatic liver tumors (43,44).

The effectiveness of RFA in the treatment of malignant liver tumors has been proven by a number of clinical studies and medical practice reports (45-48). Recently, developments in MWA technology have demonstrated its

Table 2 Baseline characteristics of studies included

First author	Country	Year	Patients (N)	Age (years)	Child-Pugh class			Tumor number		Mean tumor size (cm)	Intervention
					A	B	C	HCC	Mets.		
Randomised trials											
Shibata (11)	Japan	2006	74	65 [41-83]	55	19		83	–	1.9	RFA
Observational studies											
Livraghi (12)	Italy	2000	114	64 [53-86]	100	14	–	126	–	5.4	RFA
Buscarini (13)	Italy	2001	88	68	56	29	1	101	–	NA	RFA
Livraghi (14)	Italy	2003	2,320	NA	NA	NA	NA	NA	–	3.1	RFA
Guglielmi (15)	Italy	2003	53	68 [48-88]	24	29	–	65	–	4	RFA
Rhim (16)	Korea	2003	1,139	NA	NA	NA	NA	1,303	360	NA	RFA
Ruzzenente (17)	Italy	2004	87	68 [41-88]	48	39	–	104	–	3.9	RFA
Gillams (18)	Italy	2004	167	57 [34-87]	–	–	–	–	685	3.9	RFA
Chen (19)	China	2004	110	24-78	26	38	5	74	47	4.7	RFA
Lu (20)	US	2005	52	57	19	29	4	87	–	2.5	RFA
Lu (21)	China	2005	102	RFA: 54 [20-74]; MWA: 50 [24-74]	69	33	–	170	–	RFA: 2.6; MWA: 2.5	RFA; MWA
Raut (22)	US, Italy	2005	140	39-86	59	46	35	190	–	3	RFA
Chen (23)	China	2005	338	24-87	96	95	13	430	333	NA	RFA
Cabassa (24)	Italy	2006	59	72 [47-88]	51	8	–	68	–	3.1	RFA
Solmi (25)	Italy	2006	56	68 [45-81]	16	37	3	63	–	2.8	RFA
Choi (26)	Korea	2007	102	54 [31-73]	77	10	–	119	–	2	RFA
Poggi (27)	Italy	2007	250	63	NA	NA	NA	NA	NA	2.9	RFA
Choi (28)	Korea	2007	570	58	359	160	–	674	–	2.5	RFA
Livraghi (29)	Italy	2008	218	68	NA	NA	NA	218	–	NA	RFA
Kondo (30)	Japan	2008	2,480	NA	NA	NA	NA	NA	–	NA	RFA
Zavaglia (31)	Italy	2008	63	58	46	13	4	71	–	NA	RFA
Chen (32)	Taiwan	2008	104	58.6 [28-82]	NA	NA	NA	NA	NA	3.9	RFA
Casaril (33)	UK	2008	130	65 [33-85]	70	20	2	145	94	2.7	RFA
Sartori (34)	Italy	2008	181	60 [36-85]	NA	NA	NA	180	181	NA	RFA
Gillams (35)	UK	2008	309	64 [24-92]	–	–	–	–	NA	3.7	RFA
Liang (36)	China	2009	1,136	54 [23-83]	227	852	57	1,385	516	3.3	MWA
Solbiati (37)	Italy	2012	99	65±11.8	NA	NA	NA	–	202	2.2±1.1	–
Yu (38)	China	2011	1,462	55±11.7	447	942	73	1102	331	3.3±1.9	MWA
Kondo (39)	Japan	2010	589	68.4	396	B/C 151		–	–	2.42-2.73	RFA
Chang (40)	Korea	2010	2,630	61	NA	NA	NA	–	–	2.2	RFA
Francica (41)	Italy	2012	365	67±8	277	86	–	–	–	2.3	RFA
Lee (42)	Korea	2012	102	59.3±1	66	36	–	139	–	2.5±0.1	RFA

Age recorded as mean ± SD or median [range]. NA, not available; RFA, radio frequency ablation; MWA, microwave ablation; HCC, hepatocellular carcinoma.

Table 3 Major complications of radiofrequency ablation (RFA) and microwave ablation (MWA)

Intra-peritoneal bleeding
Portal vein thrombosis
Intra-hepatic hematomas
Bile leak
Biloma
Bile duct injury
Liver dysfunction
Liver abscess
Intestinal perforation
Diaphragmatic hernia
Hemothorax
Intractable pleural effusion
Tumour implantation

unique advantage (49,50). Although we intended to include Nano knife in our review there are no publications up to now that met our inclusion criteria and a solid conclusion could not be excreted.

Post ablation complications such as liver failure, intraperitoneal bleeding, abscess, bile duct injury, tumor seeding are very serious, and can be life threatening (51,52), other complication can prolonged hospitalization and increase morbidity. Being well aware of the complications and the choice of treatment method will lead to a more practical application and enable this procedure to be safer and more effective.

The results without heterogeneity show a mortality of 0.15% and 0.23% for RFA and MWA, respectively. The prevalence of major complications in the reported studies ranged from 1.52% to 4.7%, calculated by using a random effects model in the presence of significant heterogeneity, were 4.1% for RFA and 4.6% for MWA.

MWA-associated mortality was reported to occur in 0.002% according to a systematic review of this technique (53). Major complication rates have been reported to be higher with MWA than with RFA in a randomized trial. Our results indicated that MWA is a safe technique in terms of mortality and major complication rate. However, the results should be interpreted with caution and more reports including large number of patients are needed to make a solid conclusion.

The difference between the reported complication rates can be explained by several factors: single/multicenter studies, prospective/retrospective studies.

Prospective studies may report more accurately the number of participants lost to follow-up, the timing of collecting complications and the adequate predefined definitions for harms.

It is well understood that the risk of complications can be reduced by proficiency in technique and refinement in pretreatment assessments.

There are several strategies for decreasing complications after ablation of hepatic tumors (51). The first key strategy is prevention by not to perform ablation in patients at high risk, meticulous pre evaluation of candidates should be performed, especially in regard to coagulopathy, underlying hepatic reserve, and tumor proximity to major structures such as the bile duct or intestine. In a patient with correctable coagulopathy, ablation should be postponed until all parameters are corrected.

Early detection cannot reduce the frequency of complications such as infection or bleeding, but it can potentially minimize their clinical magnitude. Thus, the operator and other medical personnel should be knowledgeable about the spectrum of various complications after ablation because complications can be detected even during the procedure in some cases. Close immediate follow-up with clinical and laboratory data is also essential for early detection of complications.

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