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ORIGINAL ARTICLE

Radiofrequency ablation versus resection for resectable liver metastases of gastrointestinal stromal tumours: Results from three national centres in China

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KEYWORDS
Gastrointestinal stromal tumours;
Resectable liver metastasis;
Radiofrequency ablation;
Hepatic resection

Summary
Objective: The aim of the present study was to compare outcomes after curative intent radiofrequency ablation and resection in patients with resectable liver metastases of Gastrointestinal Stromal Tumours (GISTs) after pre-operative tyrosine kinase inhibitor (TKI) treatment.
Methods: We retrospectively analysed data from 25 patients diagnosed with resectable liver metastases from GISTs who received pre-operative TKI treatment, who received radiofrequency ablation or resection and post-operative TKI treatment, and who were admitted to 3 institutions from January 2009 to December 2017.
Results: Ten patients (10/25, 40.00%) underwent RFA combined with post-operative TKI treatment, and 15 (15/25, 60.00%) patients were treated with hepatic resection combined with post-operative TKI treatment. There were fewer post-operative complications (10.00% vs. 53.33%, $P = 0.04$) and shorter length of stay (4 vs. 9 days, $P = 0.00$) in the RFA group. After a median follow-up of 26 months, the 1-, 3-, and 5-year survival rates were 100.00%, 75.00%, 55.00%, respectively. The RFA group had a lower median PFS ($P = 0.007$, mPFS: 9 months versus 29 months), but overall survival was not influenced by the treatment modality compared with the resection group ($P = 0.413$, mOS: 47 months versus not reached).Hepatic resection combined with post-operative TKI treatment was the only prognostic factor for PFS in univariate analysis (HR = 0.071, 95% CI: 0.007—0.759, $P = 0.029$).

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Conclusions: For patients with resectable liver metastases from GISTs after receiving preoperative TKI treatment, compared with resection, ablation seemed to be associated with shorter progression-free survival, but RFA offered comparable overall survival, and the post-procedure morbidity and lengths of stay were significantly lower. With complete ablation of the targeted tumours, our results suggest that RFA is an acceptable option in selected patients.

Introduction

Gastrointestinal stromal tumours (GISTs) are the most frequent nonepithelial tumours of the gastrointestinal tract [1]. The liver is the most common site of metastasis from GISTs, and 20—60% of metastases occur in the liver [2,3]. The emergence of tyrosine kinase inhibitors (TKIs), such as imatinib mesylate, has radically altered the prognosis of metastatic GIST [3]. However, complete remissions are rarely observed after imatinib treatment, and progression of the disease may occur even after years of treatment [4,5]. Many centres [6,7], therefore, have started combining surgery and TKI therapy for patients with liver metastases from GISTs, the results of which have suggested that this therapy model can significantly improve patient prognosis. Radiofrequency ablation (RFA) has been found to be equivalent to that of resection in overall survival and to have lower morbidity and mortality rates in patients with small hepatocellular carcinoma (HCC) and metastases [8,9]. RFA with TKI therapy seems to be an interesting option for the treatment of liver GIST metastases.

To our knowledge, RFA and surgery are good options in the treatment of hepatic metastases from GISTs, but there is still a lack of criteria for the choice of two treatments for selected patients.There have been a few reports [10—12] on the efficacy of RFA including TKI therapy for treating hepatic metastases from GISTs. However, there is still no study examining this therapy model versus resection with TKI therapy for resectable liver metastases from GISTs. In this multicentre study, we focused on these treatments and retrospectively investigated the role of this therapy model among Chinese GIST patients with liver metastases.

Materials and methods

Patients

Twenty-five cases were admitted to 3 institutions (the Cancer Institute & Hospital, Chinese Academy of Medical Sciences, Sun Yat-sen University Cancer Center, and the First Affiliated hospital of Zhengzhou University) from January 2009 to December 2017 were identified. The inclusion criteria were that:

- the primary site had been removed and pathologically diagnosed as GIST;
- patients were diagnosed with liver metastasis from GISTs by post-operative pathology, biopsy pathology and imaging and clinical data; liver metastases were resectable after TKI treatment;
- patients received the therapeutic model of hepatic resection or RFA combined with post-operative TKI.

GIST diagnosis was verified according to the current diagnosis criteria [13]. Immunohistochemical staining was performed using antibodies against CD117, DOG-1, and CD34. The resectable criteria for liver metastasis from GISTs were the Chinese criteria for the resectability of liver metastases from colorectal cancer [14]. An indication of RF ablation was the presence of five or fewer liver tumours measuring 5 cm or smaller [2]. Synchronous metastasis was defined as the detection of a liver metastasis during diagnosis of the primary tumour or within the first six months. Data on patient demographics, clinicopathological characteristics and medical treatment with TKI and surgery for metastases were reviewed.

TKI treatment

Patients received imatinib therapy as a first-line treatment for liver metastasis. Initially, patients were orally administered 400 mg of imatinib (100-mg capsules) daily. In case of tumour progression, patient intolerance or being refractory to imatinib, the dose of imatinib was increased to 600 mg or to a maximal 800 mg per day or the treatment was switched to sunitinib. The dose of sunitinib was 37.5 mg/d. The response to TKI therapy was evaluated according to the Response Evaluation Criteria in Solid Tumours (RECIST) [15].

RFA and surgery

RFA was performed percutaneously. Patients were under conscious sedation and given local anaesthesia. US was used for guidance in all cases. The choice of RF system was left to the discretion of the operator, with features such as the size and location of the targeted metastases taken into account. Our strategy for complete necrosis of the tumour was to ablate at least 0.5 cm of the normal hepatic parenchyma surrounding the tumour as a safety margin. Successful RFA treatment was defined as the presence of a hypoattenuated area on CT and no contrast enhancement observed in this area. This hypoattenuating, non-enhanced area was considered the ablation zone and was measured in two per-

Table 1 Patient and tumour characteristics.

Item	GroupS ($n=15$)	Group A ($n=10$)	All patients ($n=25$)	P
Age < 60 years	11	9	20	0.615
Male	9	6	15	1
Primary GIST location in stomach	5	1	6	0.345
Synchronous liver metastases	4	3	7	1
Interval between imatinib to hepatic resection or RFA (months)	10 (8—36)	5 (2—15)	10 (4—24)	0.196
Responding on pre-operative treatment (RECIST)	13	9	22	1
Size of largest metastasis (cm)	3.2(2.4—5.2)	3(2.2—3.9)	3.2 (2.4—4.1)	0.495
Size of largest metastasi s < 3 cm	5	5	10	0.442
Multiple metastasis	12	8	20	1
Complication	8	1	9	0.040
Grade I-II	5	1	6	
Grade III	2	0	2	
Grade IV	1	0	1	
Length of stay (days)	9 (8-13)	4 (2.7-5.5)	7 (4.5-9)	0.000

Continuous variables are expressed as median (IQR). Binomial variables are expressed just one.

pendicular diameters. Surgical resection included the open and laparoscopic approach. The resection margin status was defined according to the International Union Against Cancer (UICC) criteria (R0: no viable tumour cells < 1 mm from the resection margin; R1: viable tumour cells < 1 mm from the resection margin; R2: macroscopic residual hepatic or extrahepatic disease). The choice of RFA and surgery was discussed at a specialist hepato-biliary multidisciplinary team (MDT) meeting. If ablation or resection were both considered technically feasible but no consensus was reached at MDT, the final decision was made by the patient in consultation with a hepatobiliary surgeon.

Follow-up and endpoints

Post-operative morbidity and length of stay were recorded, and post-operative complications were graded using the Dindo classification [16]. The follow-up included routine physical examinations, laboratory examinations, and imaging examinations. Contrast-enhanced multiphase CT or MR imaging were performed at 3 months. Overall survival (OS) was defined as the length of time from the date of hepatic resection or RFA for liver metastases to the last follow-up or death. Progression-free survival (PFS) was defined as the interval between resection or RFA for liver metastases and recurrence or progression of (residual) disease regardless of organ or tissue or death from any cause or was censored at the last follow-up.

Statistical analysis

All statistical analyses were performed using SPSS 22.0. Demographic, pre-operative and surgical data from the two groups were compared using Fisher's exact tests for categorical variables and the non-parametric Mann-Whitney U test for continuous variables. Kaplan Meier survival analysis was used to calculate OS and PFS, and significant differences between groups were evaluated using the log-rank test. Multivariable analyses of OS and PFS were performed using Cox regression models. A difference of $P<0.05$ was statistically significant.

Results

Patient demographics

From January 2009 to December 2017, a total of 25 GIST patients with liver metastases were included in this study. The median age of these patients was 53 (range 25—66) years. The majority of patients were male (15/25, 60.00%). Furthermore, the median follow-up for surviving patients was 26 months (range: 2—103 months) after liver metastases. The demographic data and tumour characteristi- cs are shown in Table 1.

Clinical and pathological characteristics

The primary GIST was located in the stomach in 6 patients (6/25, 24.00%) and in the small intestine in 19 patients (19/25, 76.00%). Furthermore, 18 (18/25, 72.00%) patients were confirmed to have metachronous liver metastases, and others had synchronous liver metastases. In all, 96.00% of patients were positive for CD117 and 84.00% of patients were positive for CD34. After pre-operative TKI treatment, the median size of the largest metastasis was 3.2 (range 1.4 to 10) cm. The median number of tumours per procedure was 2 (range 1 to 7) (Table 1).

Treatment

Before hepatic resection or RFA, pre-operative TKI treatment was given for a median of 10 (range 2 to 96) months. All patients received imatinib as pre-operative TKI therapy. Twenty-two patients responded to treatment with TKI, 9 patients had PR and 13 had SD. Three patients did not respond (PD). The response rate to TKI according to RECIST criteria was 88% (22/25). Ten patients (10/25, 40.00%)

Table 2 Prognostic factors for overall survival (OS) and progression-free survival (PFS).

Factor	Univariate analysis in OS		Univariate analysis in PFS	
	HR (95% CI)	Value *P*	HR (95% CI)	Value *P*
Age, years (< 60 vs. ≥ 60)	1.937 (0.334—11.217)	0.461	1.359 (0.278—6.645)	0.705
Sex (female vs. male)	2.370 (0.257—21.819)	0.446	1.929 (0.398—9.356)	0.415
Primary GIST location (stomach vs. small intestine)	77.976 (0.094— > 99)	0.204	6.550 (0.795—53.990)	0.081
Interval between primary diagnosis and liver metastases (synchronous vs. metachronous)	0.246 (0.034—1.800)	0.167	0.843 (0.163—4.347)	0.838
Size of largest metastasis (< 3 vs. ≥ 3)	1.074 (0.196—5.868)	0.935	1.226 (0.305—4.992)	0.774
Number of metastasis (solitary vs. multiple)	1.285 (0.147—11.276)	0.821	0.882 (0.182—4.280)	0.877
Treatment (Group A vs. Group S)	0.492 (0.087—2.778)	0.422	0.071 (0.007—0.759)	0.029

GroupA: RFA combined with post-operative TKI Group S: Resection combined with post-operative TKI.

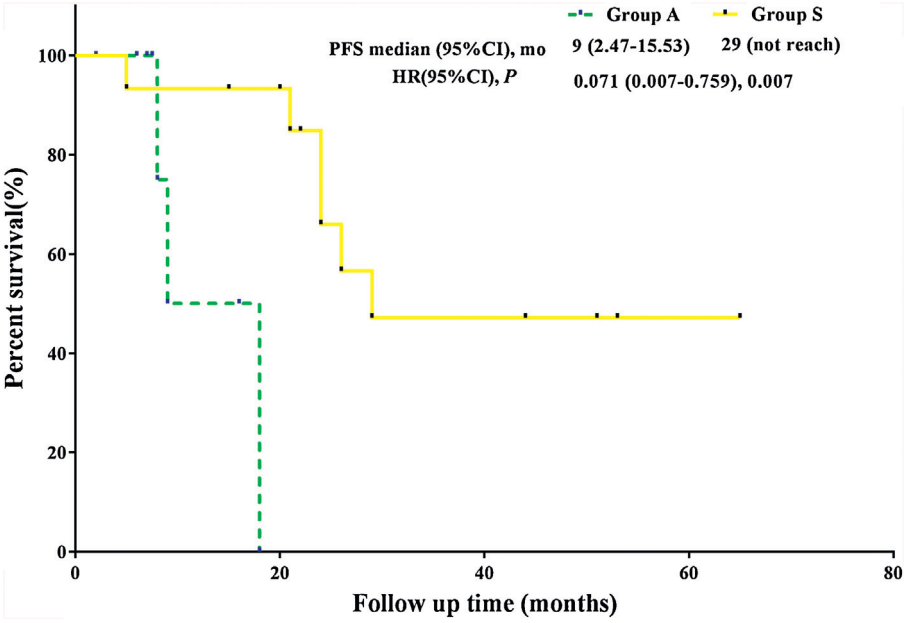

Figure 1 Progression-free survival analysis of Group A versus Group S.

underwent RFA combined with post-operative TKI treatment (group A), and 15 patients (15/25, 60.00%) were treated with hepatic resection combined with post-operative TKI treatment (group S). All patients receiving hepatic resection were R0 resections. The rate of complete ablation of the targeted tumours was 100%. After hepatic resection or RFA, the morbidity rate in this study was 36.00% (9/25), and the median length of stay was 7 days. Overall morbidity and length of stay were significantly reduced in group A: 1 (1/10,10.00%) vs 8 (8/15.53.33%) ($P = 0.04$) and 4 vs. 9 days ($P = 0.00$), respectively. In group A, the complications included only 1 minor complication. In group S, the complications included 3 major complications (pneumothorax, haemothorax, heart failure) and 5 minor complications(Table 1). 9 patients (9/25, 36%) had experienced disease recurrence. After recurrence, 4 patients received imatinib dosage adjustment, 3 patients switched to second-line sunitinib, one patient received imatinib dosage adjustment combined with RFA, and one patient received sunitinib combined with RFA.

Survival analysis

The median follow-up for surviving patients was 26 months (range: 2—103 months) after hepatic resection or RFA. The 1-, 3-, and 5-year survival rates were 100.00%, 75.00%, and 55.00%, respectively. The median OS was 73 months.6 patients (6/25, 24%) died and 9 patients (9/25, 36%) had experienced disease recurrence. Possible prognostic factors for OS and PFS are described in Table 2. The results demonstrated that after pre-operative TKI treatment, compared to patients receiving RFA and post-operative TKI(Group A), patients receiving hepatic resection and post-operative TKI (Group S) had significantly improved PFS ($P = 0.007$, mPFS: 29 months versus 9 months)(Fig. 1), but did not have significantly improved OS ($P = 0.413$, mOS: not reached versus 47 months) (Fig. 2).Hepatic resection combined with post-operative TKI treatment was the only prognostic factor for PFS in univariate analysis (HR = 0.071, 95% CI: 0.007—0.759, $P = 0.029$) (Table 2).

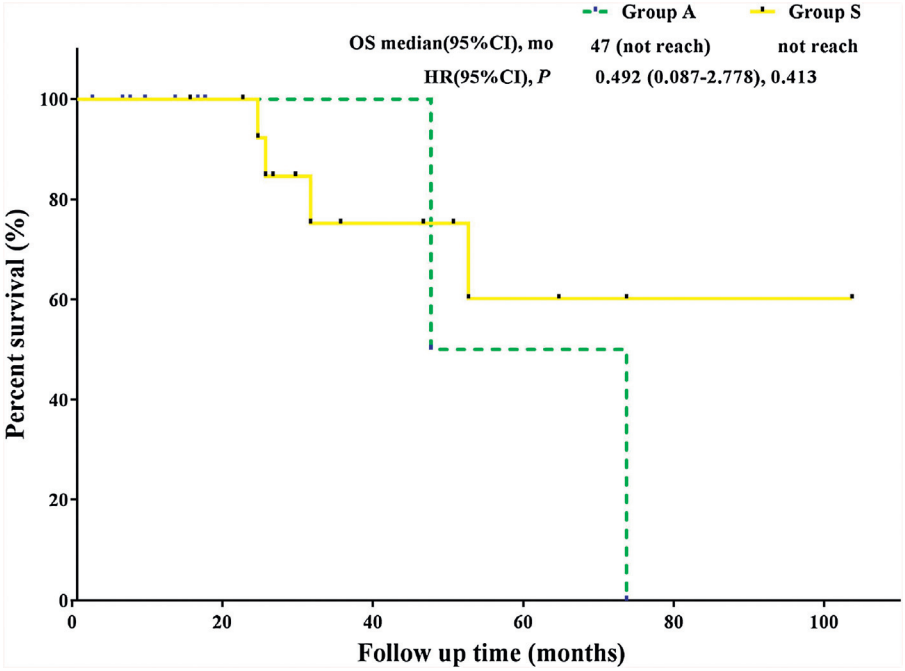

Figure 2 Survival analysis of Group A versus Group S.

Table 3 Studies on resection and RFA therapy for liver metastases from GISTs.

	Year	Author	Number of cases	Multi-modal therapies(Number of cases)
1	2010	Jones R et al. [19]	13	RFA + Systemic therapy(13)
2	2010	Xia L et al. [18]	41	Resection + TKIs(20) vs. TKIs(21)
3	2012	Turley RS et al. [1]	27	Resection + TKIs (27)
4	2013	Yamanaka T et al. [2]	7	RFA + TKIs (7)
5	2014	Bauer S et al. [6]	60	Resection + TKIs (60)
6	2014	Hakime A et al. [10]	17	RFA + TKIs (17)
7	2015	Jung JH et al. [11]	29	RFA + TKIs (29)
8	2016	Seesing MF et al. [7]	47	Resection + TKIs (41) vs. Resection (6)

Discussion

In liver metastases from GISTs, imatinib is the first-line treatment due to major improvements in survival rates, but the rarity of a complete response (CR) and secondary KIT mutations limits the use of TKIs [4,5]. The new therapy model of hepatic resection combined with TKIs was confirmed to enhance both progression-free and overall survival in selected patients with liver metastases from GISTs compared to TKIs alone [6,7] (Table 3). In patients with primary or recurrent colorectal liver metastases, RFA has been found to be equivalent to that of resection for median overall survival, with lower morbidity [9,17]. In view of the similarities in treatment between colorectal liver metastases and hepatic metastases from GISTs, RFA with TKI therapy may be an appropriate and acceptable minimally invasive alternative for multimodality management of liver metastases from GISTs.

Few authors have studied the role of RFA with TKI therapy in cases of liver metastases from GISTs. Antoine Hakime et al [10] reported that RFA should be performed at the time of best clinical response with the patient maintained on TKIs for liver metastases of GISTs. Jin-Hee Jung et al [11] suggested that RFA appears to be a safe and effective treatment for hepatic metastases from GIST when tumour progression or drug resistance occur during medical therapy. It would be better if the survival benefit from RFA combined with TKI treatment compared with a control group could be documented. Our study is the first multicentre study to examine this therapy model versus resection with TKI therapy for resectable liver metastases from GISTs.

In this study, we tried to investigate which treatment, resection or RFA combined with post-operative TKI treatment, was better for resectable liver metastases from GISTs after pre-operative TKI treatment. Our results revealed that RFA combined with post-operative TKI may be a good choice compared to resection combined with post-operative TKI. There are two reasons for this suggestion.

First, our study suggested patients treated by RFA combined with post-operative TKI treatment had lower median PFS ($P = 0.007$, mPFS: 9 months versus 29 months), but overall survival was not influenced by treatment modality

compared with patients who received resection combined with post-operative TKI treatment ($P = 0.413$, mOS: 47 months versus not reached). Unsurprisingly, patients treated with RFA had significantly lower post-procedure morbidity (10.00% vs. 53.33%, $P = 0.04$) and length of stay (4 vs. 9 days, $P = 0.00$). A worthy consideration for resection in liver metastases from GISTs is whether potential complications outweigh the small clinical benefit (PFS) in terms of survival. There is no doubt that liver resection may produce serious liver injury and blood loss, which may result in more complications. Published studies [1,7,18] reported on patients receiving resection found that the incidence of complications was 33.96% (36/106) and that the major complication rate was 14.15% (15/106), with some patients needing reoperation or interventional therapy. In this study, after liver resection, the incidence of complications was 53.33%, which included 3 major complications (pneumothorax, haemothorax, heart failure). By contrast, according to published studies [2,10,11,19], a total of 66 patients with liver metastases from GISTs received RFA. The incidence of complications was 16.67% (11/66). The major complication rate was only 4.55% (3/66), and the minor complication rate was 12.12% (8/66). The reported minor complications were treated with appropriate medical therapy. This low complication rate for RFA was confirmed in our study. RFA was well-tolerated in our cohort of patients, with only one case with minor complications (10%, 1/10). There is no doubt that a lower post-procedure morbidity and length of stay may enhance patient quality of life.

Second, the treatment of liver metastases from GISTs is a long-term and multistage process. M.F.J. Seesing et al [7] reported that 48 cases who received resection had median PFS of only 28 months, and the two-year PFS rate after RFA was only 39% in Antoine Hakime's study [10]. Our study suggested that the recurrence rate after RFA or resection was 31.03%, which was higher than the 17.49% for colorectal liver metastases [17]. All of these results suggest that the possibility of recurrence of liver metastases from GISTs after RFA or resection is high and that many patients will have to receive further treatment after recurrence. RFA can retain more normal liver parenchyma than resection. The advantages of preserving as much liver parenchyma as possible include not only decreasing the incidence of post-operative liver failure but also improving the chance of performing multimodality treatment and repeating curative treatment in case of tumour recurrence.

The premise of RFA's priority is to achieve complete ablation of targeted tumours. RFA in liver metastases from GISTs has a high rate of complete ablation. Previous studies [2,10,19] have reported complete ablation rates of 92%—100%. In the present study, the rate of complete ablation of targeted tumours was 100%. The rate was higher than 91% in colorectal liver metastases [20]. The high rate of complete ablation could be because most GIST metastases have very low echogenicity compared with other hepatic metastases, and there is a clear margin between the GIST liver metastases and the normal liver parenchyma [21], which is helpful for targeting the GIST liver metastases. Pre-operative TKI treatment increases the extent of radiofrequency (RF)-induced coagulation in GIST metastases [22]. The high complete ablation rate may promote the use of RFA for liver metastases from GISTs.

There are several limitations to our study. First, the retrospective design and small sample size are the major limitations. A prospective, randomized study with a larger sample is needed. Second, we cannot further analyse the timing of RFA after TKI treatment because there was only 1 patient who was non-responsive before RFA.

In conclusion, for patients with resectable liver metastases from GISTs after receiving pre-operative TKI treatment, RFA or resection of liver metastases from GISTs seem to offer comparable overall survival, although ablation was associated with lower progression-free survival. However, these factors must be considered alongside the fact that RFA had a much lower rate of complications, a shorter length of stay and improved the chance of performing multimodality treatment in cases of tumour recurrence. Under complete ablation of targeted tumours, our results suggest that RFA is an acceptable option in selected patients.

Ethics approval and consent to participate

The research protocol was approved by the Institutional Review Board of the Cancer Hospital of Chinese Academy of Medical Sciences. Informed consent was obtained from all patients.

Contributions

Conception and design: Jianguo Zhou, Jianqiang Cai.

Administrative support:Hong Zhao, Jianjun Zhao, Xinyu Bi, Zhiyu Li.

Provision of study materials or patients:Zhen Huang, Yefan Zhang.

Collection and assembly of data:Qichen Chen, Cong Li, Han Yang.

Data analysis and interpretation: Qichen Chen, Cong Li, Han Yang.

Manuscript writing: all authors.

Disclosure of interest

The authors declare that they have no competing interest.

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