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MR-guided Interstitial Laser Thermotherapy of Colorectal Liver Metastases: Efficiency, Safety and Patient Survival

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Abstract

Purpose: Evaluation of MR-guided interstitial laser thermotherapy (ILT) of colorectal liver metastases under consideration of efficacy, safety and patient survival.

Materials and Methods: Sixty-six inoperable patients with a total of 117 colorectal liver metastases were treated with MR-guided laser therapy in 96 sessions. 40.9% of patients presented metastases from rectum carcinoma, 30.3% from sigmoid carcinoma and 28.8% from colon carcinoma. Inclusion criteria were ≤ 5 metastases ≤ 5 cm in greatest diameter and no extrahepatic tumor spread. Internally water-cooled 9F power-laser-applicators were placed under CT-fluoroscopy. For MR-guided ILT, a 1064 nm Nd-YAG-lasers with a beam divider with multi applicator technique was used. The energy applied was 10 watt per centimeter diffusor length, with the diffusor length ranging from 20 to 40 mm. The mean duration of the energy application was 23 minutes (range: 15 – 37 minutes). The endpoint of the laser ablation was defined as the absence of hyperintense tumor tissue in the continuously monitored T2-w fat saturated gradient-echo sequences. Follow-up included contrast-enhanced MRI using T1- and T2-weighted spin-echo and gradient-echo sequences every three months after treatment. Survival times were calculated using the Kaplan-Meier method.

Results: The median follow-up was 8.7 months (mean 11.8; standard deviation 9.9; range 1 to 36). The overall median progression free survival was 6.1 months (range, 0.3 to 27+ months). Median survival was 23 months (95% CI, 17-29 months). The rate of major complications was 2.1% (n = 2) and peri-procedural mortality (30 days) was 3% (n = 2). After 3, 6, 9, and 12 months, local tumor control was 98.3%, 91.4%, 76.1%, and 69.4%, respectively. In no patient metastatic deposits along the catheter access route were found.

Conclusions: In patients with colorectal liver metastases, interstitial laser thermotherapy is an effective and safe therapeutic option and therefore suitable not only in palliative situations.

Key words: colorectal cancer, liver metastases, interventional MRI, interstitial laser thermotherapy

Introduction

Although surgical resection is the gold standard for the treatment of colorectal liver metastases, only 10% to 30% of the patients are candidates for resection because of extensive disease or medical comorbidities. The remaining patients undergo systemic chemotherapy [19]. About 60% of patients with surgical liver resection sustain a recurrence of intrahepatic metastases [18]. Over the past few years several percutaneous, image guided nonsurgical tumor therapies have been introduced as treatment alternatives mainly in patients not eligible for surgical resection. Besides locoregional treatments by chemoperfusion or chemoembolisation, methods for local tumor destruction comprise radiofrequency ablation, cryotherapy, interstitial laser thermotherapy (ILT) and CT-guided brachytherapy [9, 17, 17, 21, 23].

To this day, no data exists comparing the outcome of different minimal invasive techniques for the ablation of liver metastases directly. Some more recent publications focus on comparisons of survival data with historical controls [24]. However, reports on local tumor ablation often mix various tumor entities, or they ignore the influence of adjuvant treatment. In light of recent advances in the systemic treatment of colorectal carcinoma, the use of historical controls to assess survival is problematic. A rather independent success indicator to compare ablative techniques probably is long term local tumor control.

In this study, we report our long experience with ILT of colorectal liver metastases.

Material and Methods

Patients

Sixtysix patients [mean age 65 years; range 46-82 years; 44 (66.7%) male; 22 (33.3%) female] with 117 (median 1; range 1-3) colorectal liver metastases were treated in 96 (median 1; range 1-4) sessions using 307 (median 3; range 1-5) water-cooled Power-Laser-Applicators (Somatex, Berlin, Germany or Trumpf, Saalfeld, Germany). 40.9% of the patients presented metastases from rectal carcinoma, 30.3% from sigmoid carcinoma and 28.8% from colon carcinoma. Inclusion criteria of unresectable metastases were ≤ 5 cm in greatest diameter and no extrahepatic tumor spread. Eighteen patients (27.3%) had undergone hemihepatectomy and 13 (19.7%) had an atypical partial liver resection with a median interval of 18 months between surgery and laser treatment. Sixteen patients (24.2%) had bilobar disease and 11 more than 3 metastases. Thirtyfive patients (53%) presented synchronous metastases. Before performing the intervention, the size of metastases was determined on the native axial T1-w MRI-sequence by measurement of the longest diameter. The median tumor size was 29 mm (mean 31 mm; standard deviation 10; range: 14-50 mm). All patients gave written consent before inclusion into the study.

Interstitial Laser Thermotherapy (ILT)

Conscious sedation and pain relief by i.v. application of midazolam and fentanyl according to the individual pain or discomfort level of the patient were provided during the whole procedure. Internally water-cooled 9F power-laser-applicators were placed under CT-fluoroscopy and previous application of local anesthesia. Thereafter, the patients were transferred to the MR imaging unit for image guided ILT. A 1064 nm Nd-YAG-lasers (MediLas 5060 und 5100, Dornier, Germany; MY 80, Trumpf, Germany) with a beam divider that allowed the simultaneous use of up to 6 laser fibers (multi applicator technique) was used. The energy applied was 10 watt per centimeter diffusor length, with the diffusor length ranging from 20 to 40 mm. The energy delivery was tested before each intervention using a wattmeter (MY Test, Trumpf, Germany). The mean duration of the energy application was 23 minutes (range: 15 – 37 minutes). The laser application was monitored continuously by T2-w gradient-echo MR imaging for nearly online thermometry (Gyroscan 1.5T, Philips, Best, The Netherlands). This sequence was used to define the duration of the ablation. A repositioning of the laser application was performed if deemed necessary under MR monitoring. The endpoint of the ablation was the absence of hyperintense tumor tissue in T2-w fat saturated gradient-echo sequences. After the procedure, the puncture tract was closed with fibrin tissue glue (Tissucol Duo S; Baxter, Unterschleissheim, Germany).

Magnetic Resonance Imaging (MRI)

All studies were performed with a 1.5-T MRI (Gyroscan 1.5T, Philips, Best, The Netherlands). All patients were examined by plain and Gd-BOPTA enhanced T1-w and T2-w MRI sequences before and every 3 months following the ILT (Fig. 1-2). Imaging was also performed at any time if tumor progression was clinically suspected.

The specific MRI sequences for the study protocol were:

- T2-w TSE FS (TE = 90 ms, TR = 2100 ms, flip angle = 90°), Matrix 512x512
- T1-w TSE (TE = 5 ms, TR = 30, flip angle = 30°), Matrix 256x512
- T1-w TSE (TE = 5 ms, TR = 30, flip angle = 30°) 20s p.i. von 0.05 mmol/kg Gd-BOPTA
- T1- w TSE (TE = 5 ms, TR = 30, flip angle = 30°) 2h p.i. von 0.05 mmol/kg Gd-BOPTA.

Definitions

Local recurrence was defined as an increase of lesion size (>25%) depicted on MRI as hypointense lesions on T1-w sequences and hyperintense lesions on T2-w sequences with a broad contact to the coagulation zone [14] or with a distance of the center of mass of less than 1 cm. No time limit was applied for the occurrence of a local tumor recurrence.

Statistical Analysis

The local tumor control for each metastasis and the survival rate for all patients were calculated at the date of local laser treatment. The Kaplan-Meier method was used to obtain survival rates and the Log Rank test for testing survival distributions as subset analysis to calculate the statistical significance of differences between the groups (SPSS Version 11.0.1, SPSS Inc., Chicago, USA). A p-value of <.05 was considered as statistically significant.

Results

Local Tumor Control, Reinterventions and Subsequent Therapies

The median follow-up was 8.7 months (mean 11.8; standard deviation 9.9; range 1 to 36). The overall median progression free survival was 6.1 months (0.3 to 27 months). After 3, 6, 9, and 12 months, the local tumor control was 98.3% 91.4%, 76.1%, and 69.4%, respectively.

Immediately after the first laser ablation, adjuvant chemotherapies were applied in 4.6% of patients despite the fact that local tumor ablation had been recorded as complete and no extrahepatic disease had been documented. All other patients did not receive chemotherapy until evidence of tumor progression occurred. Among those 4.6% of patients with adjuvant chemotherapy, 15.2% had not undergone prior chemotherapy, 46.9% had undergone 1 and 37.9% had undergone more than 1 previous chemotherapy regimen. During follow up, thirty eight patients (57.8%) required a hepatic reintervention by CT-guided brachytherapy in case of local recurrence (31.8%; n = 21) or/and new intrahepatic metastases. Eighteen patients (27.3%) received a hepatic arterial port system for local chemotherapy (hepatic arterial infusion, HAI), 5 (27.8%) before (downstaging) and 13 (72.2%) after treatment in case of multifocal hepatic without extrahepatic tumor progression.

Upon tumor progression, most patients underwent an initiation (15.2%, n = 10) or reinitiation (66.7%, n = 44) of systemic chemotherapy. Overall 81.8% (n = 54) underwent systemic chemotherapy, 62.5% as first, 31.3% as second and 6.3% as third line chemotherapy. Twelve patients (18.2%) were lost for follow up with respect to details of adjuvant chemotherapy treatment.

Complications

The most frequent complications were pain (16.6%), pleural effusion (15.6%) and small subcapsular hematomas (13.5%), all rated clinically not relevant. Severe complications were limited to 2 patients (3%). The periprocedural mortality at day 30 post intervention was 3% (n = 2, diagnoses: pulmonary embolism after 4 weeks and sepsis after 3 weeks) (Table 1). In no

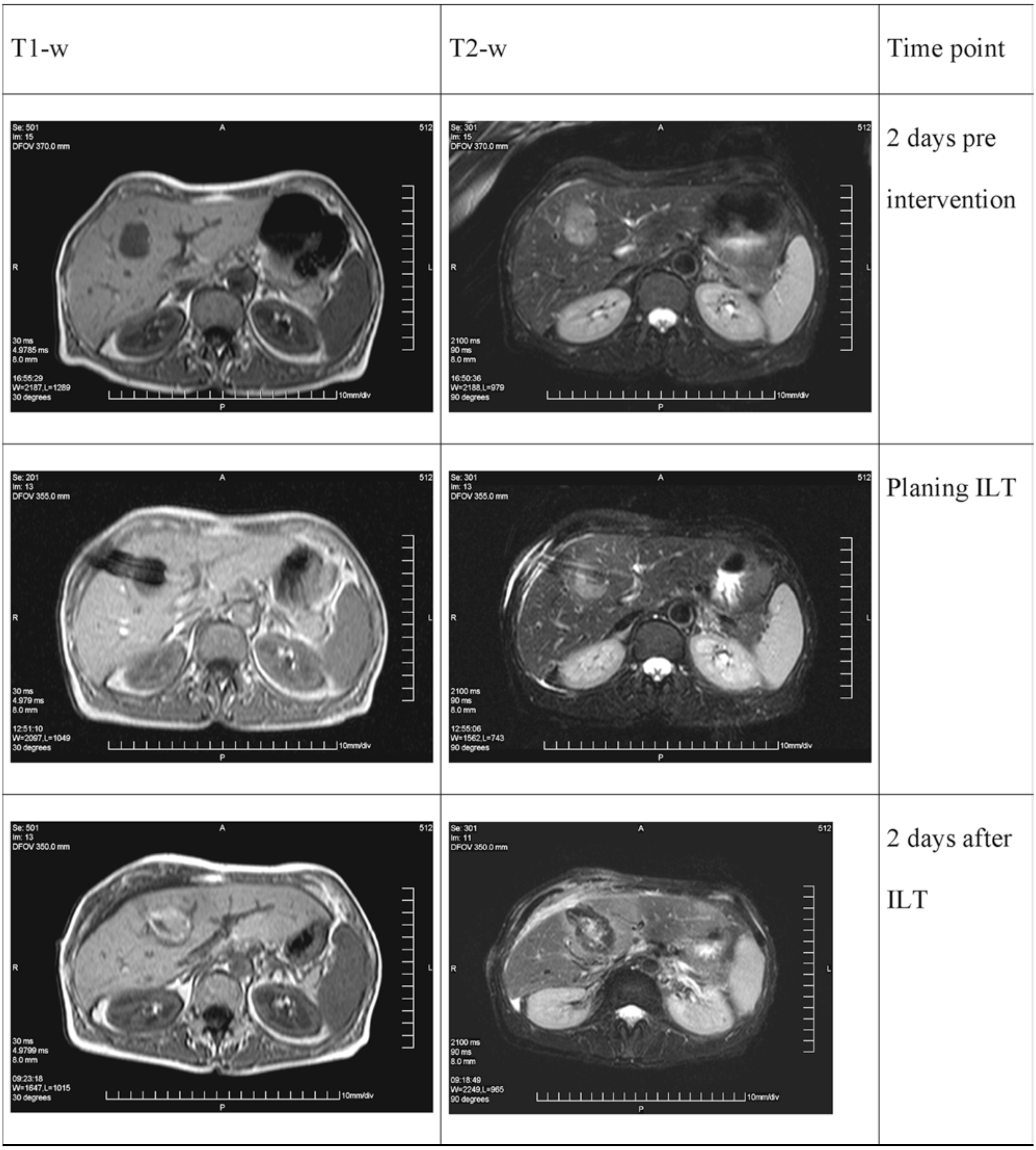

Fig. 1. T1-w and T2-w MRI as peri-interventional setup. 65 years old famel patient with singular metastasis of sigmoid carcinoma 15 months after surgery and systemic first line chemotherapy (T3N2M1). ILT-treatment with two laser catheter with typical coagulation zone two days after intervention.

patient we depicted metastatic deposits along the previous access route for laser ablation.

Survival Analysis

The median overall progression free survival was 6.1 months (range, 0.3 to 27 months). The median cumulative survival of all patients (including periprocedural mortality at day 30 p.i.) was 23 months from the time of intervention [95% CI 16.8 – 28.74 months (1-year survival, 74%, 2-year survival 44%, 3-year survival 18%)], respectively (Fig. 3).

A comparison of survival rates from the time of intervention between patients with colorectal carcinoma with synchronous versus metachronous metastases showed no statistically significant differences (Log Rank test: $p = 0.23$) (Fig. 4).

There were no statistically significant differences between survival rates of patients with unilobar vs. bilobar metastases (Log Rank test: $p = 0.99$) (Fig. 5) or

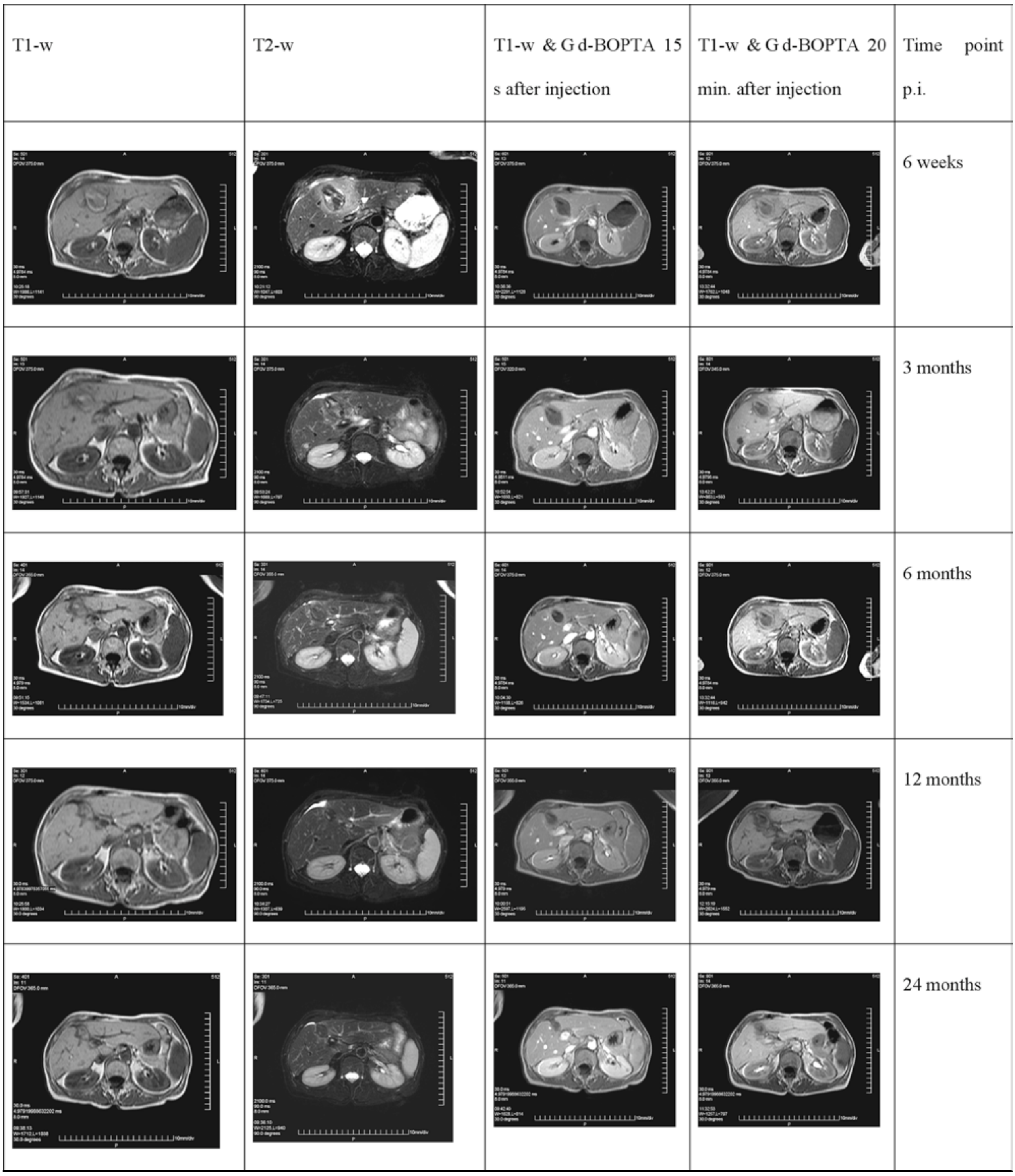

Fig. 2. T1-w, T2-w, and Gd-BOPTA enhanced MRI as follow up in same patient as fig. 5. No local recurrence after ILT after intervention around typical shrinking coagulation zone in 24 months.

between patients with less/equal versus more than 3 metastases at the time of first treatment (Log Rank test: p = 0.48) (Fig. 6).

Discussion

In this study, the use of percutaneous, image-guided interstitial laser ablation for the treatment of colorectal liver metastases was assessed. Our results were favorable with a high rate of local tumor control and very few major complications.

Today, there exists no prospective data on the effect of local tumor ablation on survival. More recently, Berber et al. [1] have published a study evaluating prognostic factors for radiofrequency ablation (RFA) treatment of colorectal liver metastases. They concluded that the carcinoembryonic antigen (CEA) level, the tumor size and the number of tumors affected

Table 1. Complications after interstitial laser therapy - 66 patients with 117 colorectal metastases.

Complications - Major	
Seizure	1 % (n = 1)
Liver abscess	1 % (n = 1)
Complications - Minor	
Pain	16.6 % (n = 16)
Pleural effusion	15.6 % (n = 15)
Subcapsular hematoma	13.5 % (n = 13)
Arrhythmia	6.2 % (n = 6)
Nausea/vomiting	3.1 % (n = 3)
Respiratory depression	3.1 % (n = 3)

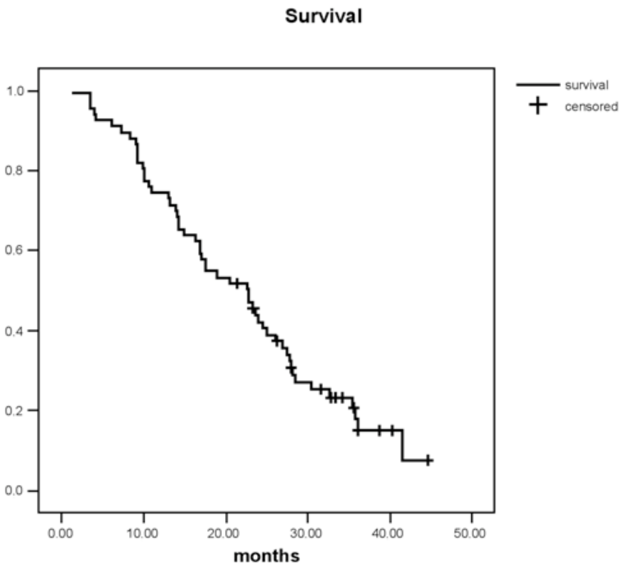

Fig. 3. Cumulative survival for all patients from the time of intervention (Median: 23 months; CI-95%: 16.8-28.74)

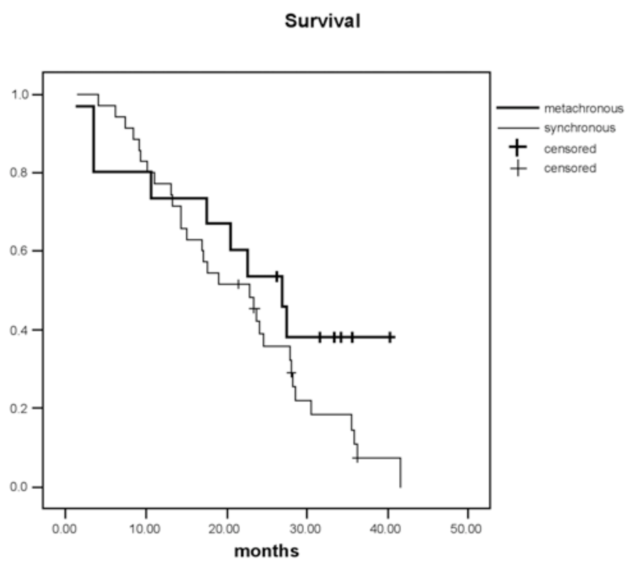

Fig. 4. Comparison of cumulative survival between synchronous and metachronous metastatic processes from the time of intervention (Log Rank = 0.22)

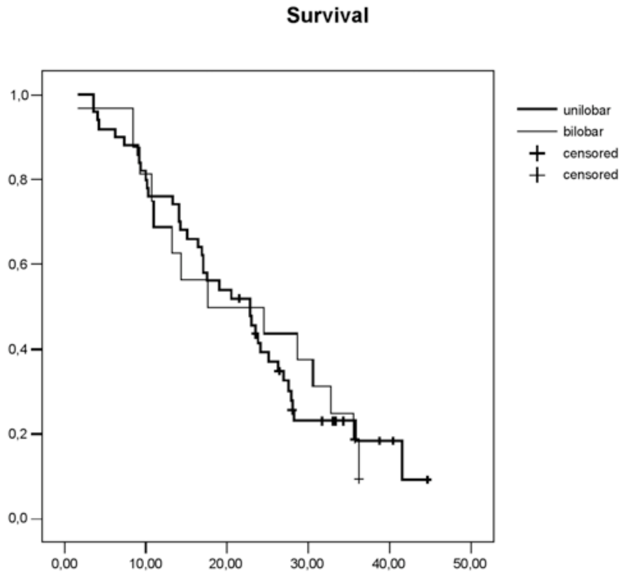

Fig. 5. Comparison of cumulative survival between unilobar und bilobar metastatic processes from the time of intervention (Log Rank = 0.99)

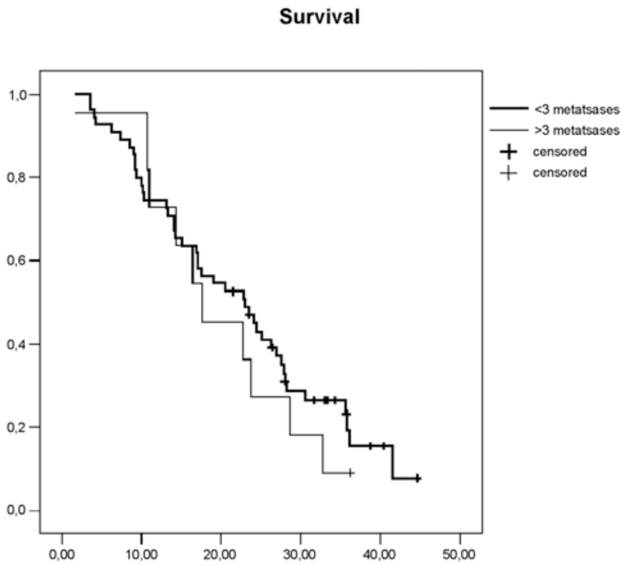

Fig. 6. Comparison of cumulative survival between patients with less vs. more then 3 liver metastases from the time of intervention (Log Rank = 0.48)

survival after thermal ablation. Moreover, in their study limited amounts of extrahepatic disease did not appear to influence survival adversely [1]. Conversely, residual tumor after surgical resection as indicated by a positive resection margin in histopathology has been demonstrated to be an independent predictor of poor prognosis [6, 20]. It remains unclear, if local tumor recurrence after local ablation has a negative impact on survival and/or deliberate incomplete tumor destruction (i.e. tumor debulking) has a positive impact if any impact on the prognosis. The only undisputed fact remains that repetitive approaches to recurrent local or other intrahepatic disease is better and more frequently possible with the minimal-invasive technique.

Nevertheless, the relatively low overall survival in our study with a median of 23 months is conspicuous. Disease free as well as long term survival were inferior compared to data published by Vogl et al. [24] or Christophi et al. [2] for laser ablation of colorectal liver metastases. We believe that our study population had a negative selection bias linked to a poor prognosis. Whereas in our study population almost 50% of patients had already undergone previous liver surgery for metastasis (thus demonstrating recurrent disease), only 26% and 37% had previous liver surgery in the studies of Christophi et al. [2] and Vogl et al. [24], respectively. A negative selection bias in our study population is also demonstrated by the short duration of disease free survival in our study group (median: 6 months) compared to Christophi et al. [2] (median: 25 months).

Following hemihepatectomy or complete resection, Scheele et al. [20] reported a median survival of 43.6 months with negative histopathologic margins (RO) of colorectal liver metastases. Ohlson et al. reported a median survival of 36 months again after liver resection [12, 19]. A significant factor contributing to the lower median survival rate in our study is the inclusion of patients with poor prognostic factors such as multiple bilobar metastases. In addition, one third of the study population had previously undergone open hepatic resection, indicating a selection bias with patients displaying recurrent liver disease. Data by Ercolani et al. [5] have described a 3-year-survival rate of 43% for a study population undergoing surgical resection despite relative contraindications, such as multiple bilobar metastases. Our own results for laser ablation of colorectal metastases are inferior with a 3-year-survival rate of 18%.

With respect to prognostic factors our results are in concordance with previous literature describing outcome post liver resection. We found no significant differences between survival rates for a number of metastases ≤ or > than 3, synchronous and metachronous hepatic deposits, or mono- and bilobar localization [12].

In order to establish a success indicator to compare local ablation strategies, local tumor control seems to be a rather independent variable, if no time limit is applied and if the influence of adjuvant therapies is appreciated accordingly. In our study group, the influence of adjuvant chemotherapy has probably been low within a minor portion of 4.6% of patients receiving such treatment. These adjuvant chemotherapies had been applied despite the fact that local tumor ablation had been recorded as complete and no extrahepatic disease had been documented. These decisions for adjuvant treatment were taken by refering oncologists based on individual considerations.

Our results for laser ablation with a local tumor control of 91% and 69% after 6 and 12 months (Kaplan-Meier) differ from previously published results. Vogl et al. [24] have published extensive data on laser ablation of liver metastases over the past years, with a local tumor control for colorectal tumors of more than 95% at 6 months and no further local recurrence later than 6 months. Clearly, the categorization of regrowing tumor as local progression depends on details of the definition as rendered by us in the section "materials and methods", including tumor growth with a center of mass at a distance of ≤ 10 mm from the ablated tumor. In colorectal liver metastases, microsatellites beyond the macroscopic tumor border are found frequently in histopathological specimen [13]. The presence of microsatellites as well as their distance to the originating metastasis have been linked to the presence of a pseudo-capsule, the extent of lymphocyte infiltration between metastasis and liver parenchyma, and the morphologic type of the lesion [11, 13, 25]. Nanko et al. [11] described a mean distance of the microsatellites to the margin of the originating metastases of 7.5 mm ± 8 mm. It is very likely that different definitions of local tumor recurrence versus new tumor manifestations adjacent to the ablated tumor volume have contributed to the outcome variations after laser ablation in our study compared to those results by Vogl et al. [24].

In comparison to other thermal ablation techniques such as RFA, results after laser ablation seem to be highly competitive. Solbiati et al. [22] have described local control after RFA of colorectal liver metastases in 66% of 22 patients with maximum tumor diameters of 4.5 cm. Progression-free survival was 50% and 33% after 12 and 18 months, with an overall survival of 94% and 89%, respectively. Adjuvant therapies were not documented in detail. In an extension of these data, in 2001 the same group reported on 117 patients with maximum tumor diameters of up to 9 cm (Ø 2.6 cm) [23]. In this larger series, local tumor control was 61% and the median progression-free survival was 12 months. At 12 months follow up, in 44 patients with colorectal liver metastases, De Baere et al. [4] demonstrated a local tumor control of 79% after 33 percutaneous RFA treatments under ultrasonographic guidance. Eleven patients treated intraoperatively with simultaneous Pringle-maneuver (to reduce liver perfusion and related cooling effects) showed a local tumor control of 91%. The average tumor diameter was 2.6 cm for percutaneous RFA and 1.3 cm for patients treated intraoperatively.

The complication rate in our series was higher than reported by Vogl et al. (overall complication rate was 1.5%; 30-day mortality n = 2) [24]. However, we believe that our results justify the procedure being called as associated with a moderate rate of complications, specifically since most events were minor or even clinically occult such as all cases of pleural effusion detected only through postinterventional screening. Two major events leading to perioperative deaths reflect the severe comorbidity of the oncological patient population rather than technical failures, with a pulmonary embolism as well as an unclear sepsis occuring well after discharge. As stated previously, the experience of the interventionalists with ILT was high and should not have been a limiting factor.

Percutaneous thermal tumor ablation has major drawbacks. First, limitations exist for thermal ablation of hepatic lesions located close to the bile duct bifurcation due to the risk of inadvertent injury and severe biliary complications [15]. Second, large blood vessels adjacent to the tumor or strong tumor perfusion account for adverse cooling effects, potentially prohibiting complete tumor ablation. Mulier et al. [10] describe that by applying a Pringle-maneuver during intraoperative ablation, the therapeutic effect can be enhanced significantly. Percutaneous embolisation or temporary balloon occlusion of liver vessels have been described by interventional radiologists to mimic the effect of the Pringle-maneuver. However, these approaches add severe complexity to the overall procedure and thus have not found their way into clinical routine [7, 8, 16]. Third, most authors [3, 7] believe that RFA or laser ablation is limited to maximum lesion diamters of approximately 5 cm, if complete tumor ablation is intended. This should be modified considering the fact that multiple electrodes can be used, thus increasing the area of ablation. A reasonable alternative in those cases unfavorable for thermal ablation may have evolved with the introduction of image guided brachytherapy [17].

This sudy is limited in certain respects. The results of our patient population included data on surgical resection and previous and adjuvant chemotherapy treatments. Recent advances in systemic chemotherapy for liver metastases probably have influenced the outcome of our study population. Therefore, the effect of local laser tumor ablation for patient survival as a standalone treatment or as an adjunct to chemotherapy remains unclear. However, we do not believe that a comparison with historical data of patients undergoing either surgical resection or systemic chemotherapy alone is authoritative, specifically in light of the heterogeneity of our patient population with respect to adjuvant treatment.

MR-guided interstitial laser thermotherapy of colorectal liver metastases is an effective and safe therapeutic option not only in a palliative situation.

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