MRI in addition to CT in patients scheduled for local therapy of colorectal liver metastases (CAMINO) an international, multicentre, prospective, diagnostic accuracy trial

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Summary

Background Guidelines are inconclusive on whether contrast-enhanced MRI using gadoxetic acid and diffusion-weighted imaging should be added routinely to CT in the investigation of patients with colorectal liver metastases who are scheduled for curative liver resection or thermal ablation, or both. Although contrast-enhanced MRI is reportedly superior than contrast-enhanced CT in the detection and characterisation of colorectal liver metastases, its effect on clinical patient management is unknown. We aimed to assess the clinical effect of an additional liver contrast-enhanced MRI on local treatment plan in patients with colorectal liver metastases amenable to local treatment, based on contrast-enhanced CT.

Methods We did an international, multicentre, prospective, incremental diagnostic accuracy trial in 14 liver surgery centres in the Netherlands, Belgium, Norway, and Italy. Participants were aged 18 years or older with histological proof of colorectal cancer, a WHO performance status score of 0–4, and primary or recurrent colorectal liver metastases, who were scheduled for local therapy based on contrast-enhanced CT. All patients had contrast-enhanced CT and liver contrast-enhanced MRI including diffusion-weighted imaging and gadoxetic acid as a contrast agent before undergoing local therapy. The primary outcome was change in the local clinical treatment plan (decided by the individual clinics) on the basis of liver contrast-enhanced MRI findings, analysed in the intention-to-image population. The minimal clinically important difference in the proportion of patients who would have change in their local treatment plan due to an additional liver contrast-enhanced MRI was 10%. This study is closed and registered in the Netherlands Trial Register, NL8039.

Findings Between Dec 17, 2019, and July 31, 2021, 325 patients with colorectal liver metastases were assessed for eligibility. 298 patients were enrolled and included in the intention-to-treat population, including 177 males (59%) and 121 females (41%) with planned local therapy based on contrast-enhanced CT. A change in the local treatment plan based on liver contrast-enhanced MRI findings was observed in 92 (31%; 95% CI 26–36) of 298 patients. Changes were made for 40 patients (13%) requiring more extensive local therapy, 11 patients (4%) requiring less extensive local therapy, and 34 patients (11%) in whom the indication for curative-intent local therapy was revoked, including 26 patients (9%) with too extensive disease and eight patients (3%) with benign lesions on liver contrast-enhanced MRI (confirmed by a median follow-up of 21·0 months [IQR 17·5–24·0]).

Interpretation Liver contrast-enhanced MRI should be considered in all patients scheduled for local treatment for colorectal liver metastases on the basis of contrast-enhanced CT imaging.

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See Comment page 9

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Introduction

Liver metastases are a major prognostic factor for survival in patients with colorectal cancer. Approximately 20–25% of all patients with colorectal cancer have liver metastases at presentation (synchronous) or during follow-up (metachronous).[1–4] Local therapies such as surgical resection and local thermal ablation are the best treatment options to improve overall survival.[2,3,5,6] Pre-interventional imaging of colorectal liver metastases is crucial to decide on the most effective local therapy.

The standard diagnostic investigation of patients with primary or recurrent colorectal liver metastases consists of abdominal contrast-enhanced CT.[7,8] Contrast-enhanced MRI is increasingly utilised in addition to contrast-enhanced CT, as liver contrast-enhanced MRI is more accurate in detecting colorectal liver metastases,

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Research in context

Evidence before this study

We did an extensive literature search using PubMed, Embase, and the Cochrane Library for studies published between Jan 1, 1990, and May 20, 2023. We used the search terms "colorectal liver metastases", "magnetic resonance imaging", and "treatment plan" and synonyms. We included studies in any language concerning change in local treatment plan based on the additional findings of contrast-enhanced MRI following CT in patients with colorectal liver metastases, compared with contrast-enhanced CT only. We identified two randomised controlled trials, one retrospective diagnostic accuracy study, five prospective and three retrospective cohort studies, and one systematic review. The two randomised controlled trials included 13 and 17 patients relevant for our research question and were not designed or powered for the effect of liver contrast-enhanced MRI on the local treatment plan. The largest prospective cohort study included 51 patients with colorectal liver metastases who received contrast-enhanced CT followed by gadoxetic acid-enhanced liver MRI with diffusion-weighted imaging. The authors reported a change in surgical plan in 45% of the patients. All patients were treated with preoperative chemotherapy, change in local treatment plan was not the primary outcome, and details on the exact change in surgical treatment (ie, more or less extensive surgery or no surgery) based on liver contrast-enhanced MRI findings were not reported. The other studies also had numerous limitations (eg, small number of patients and retrospective study design), but they all showed promising results with regards to the clinical effect of liver contrast-enhanced MRI.

Added value of this study

To our knowledge, this is the first international, multicentre, prospective, incremental diagnostic accuracy trial to assess the clinical effect of an additional gadoxetic acid-enhanced liver MRI with diffusion-weighted imaging on the local treatment plan in patients with colorectal liver metastases amenable to local treatment based on contrast-enhanced CT. Because a randomised controlled trial comparing abdominal CT and liver MRI versus CT was considered not feasible due to the high use of liver contrast-enhanced MRI in current daily practice, our trial provides the highest level of evidence showing that liver contrast-enhanced MRI changed the local treatment plan in about a third of patients with colorectal liver metastases scheduled for local therapy based on contrast-enhanced CT.

Implications of all the available evidence

On the basis of the results of this study, we expect that guidelines will further highlight and advise the use of liver MRI in the diagnostic investigation of patients with colorectal liver metastases amenable for local treatment based on contrast-enhanced CT. Of note, our study did not include a comprehensive cost-effectiveness analysis or the effect of change in clinical management on long-term outcomes such as disease-free survival and overall survival. These should be assessed in future analyses but would ultimately require a large multicentre randomised trial. Given the existing, established use of liver contrast-enhanced MRI in daily clinical practice at several hospitals before the start of our trial, this was considered not feasible or ethical.

especially for lesions smaller than 10 mm.[9,10] Technological improvements have further enhanced the diagnostic accuracy of liver contrast-enhanced MRI, with the combination of diffusion-weighted imaging and use of gadoxetic acid as contrast medium having the highest sensitivity.[10,11]

Evidence on the clinical effect of an additional liver contrast-enhanced MRI on the pre-interventional local treatment plan of patients with colorectal liver metastases is scarce. The American College of Radiology Appropriateness Criteria indicate that staging of colorectal liver metastases can involve both contrast-enhanced CT and liver contrast-enhanced MRI, but also emphasises the paucity of current literature on the subject.[12] Several European guidelines recommend liver contrast-enhanced MRI, but these recommendations are based on imaging accuracy and not on documented evidence on the added value of contrast-enhanced MRI.[8,13–15]

We aimed to assess the clinical effect of an additional liver contrast-enhanced MRI on the local treatment plan in patients with colorectal liver metastases amenable to local treatment, based on contrast-enhanced CT. We determined the minimal clinically important difference in the proportion of patients who would have change in their local treatment plan due to an additional liver contrast-enhanced MRI to be 10%. We also aimed to develop and validate a clinical prediction rule for the use of contrast-enhanced MRI in patients with colorectal liver metastases amenable to local therapy, based on contrast-enhanced CT.

Methods

Study design and participants

This CAMINO study was an international, multicentre, prospective, incremental diagnostic accuracy study. The study was performed in 14 liver surgery centres in the Netherlands, Belgium, Norway, and Italy (appendix p 9). All participating centres had formal regular multidisciplinary team meetings at least once per week to discuss patients with colorectal liver metastases. All participating centres and involved abdominal radiologists, surgeons, and interventional radiologists had extensive experience in the pre-interventional investigation of patients with colorectal liver metastases.

Patients aged 18 years or older with histological proof of colorectal cancer, a WHO performance status score of 0–4, and primary or recurrent colorectal liver

metastases who during a formal multidisciplinary team meeting were considered candidates for local therapy on the basis of abdominal contrast-enhanced CT, were invited to participate in the study. Local therapy was defined as surgical resection, local thermal ablation, or a combination of surgical resection and intra-operative thermal ablation. Exclusion criteria were contraindication for liver surgery or local thermal ablation, extrahepatic colorectal metastases on contrast-enhanced CT and no realistic option for curative therapy, unresectable primary tumour or resectable primary tumour requiring immediate surgery, and patients with contraindications for the use of liver contrast-enhanced MRI or gadoxetic acid.[16,17] The study complied with the Declaration of Helsinki (64th version; October, 2013) and the guidelines of Good Clinical Practice. The institutional review board of the Amsterdam UMC and all participating centres approved the study protocol.[18] All participants provided written informed consent for study participation and the use of individual patient data for study purposes.

Procedures

In each participating centre, study participants underwent an abdominal contrast-enhanced CT followed by a liver contrast-enhanced MRI (imaging parameters described in the appendix [pp 10–16]). All CT scans were contrast-enhanced and included at least a portal venous phase. Liver contrast-enhanced MRI scans included at least a T2-weighted sequence, diffusion-weighted imaging, and multiphase T1-weighted sequence with gadoxetic acid (Primovist, Bayer AG, Berlin, Germany) as a contrast agent. Hepatic steatosis on contrast-enhanced CT and liver contrast-enhanced MRI were diagnosed according to predefined criteria (appendix p 2). The maximum time interval between contrast-enhanced CT and actual local therapy was 10 weeks. Imaging assessment and weekly multidisciplinary team meetings were performed on site. Liver contrast-enhanced MRI (ideally performed within 4 weeks of contrast-enhanced CT) was assessed by an abdominal radiologist who was not masked to contrast-enhanced CT results, since liver contrast-enhanced MRI is performed in addition to contrast-enhanced CT in daily clinical practice.

During the multidisciplinary team meeting, first, a detailed local treatment plan based on contrast-enhanced CT only was proposed and documented (electronic case report form). The detailed local treatment plan included the exact localisation, number, and extent of resection or ablation. Second, the liver contrast-enhanced MRI was presented, and the precise local treatment plan based on contrast-enhanced CT and liver contrast-enhanced MRI combined was decided and reported in the electronic case report form. This was either at the same multidisciplinary team meeting or the following meeting, depending on the availability of contrast-enhanced MRI. Decisions on the local treatment plan were based on number of lesions, size of lesions, localisation of lesions, and vascular involvement. Using contrast-enhanced intraoperative ultrasound during surgery was not mandatory but was done per routine clinical practice.

Data were collected using a web-based database management system with predefined electronic case report forms (ALEA, FormsVision, Abcoude, Netherlands). Baseline data, including sex, were extracted from the electronic patient record.

An independent centralised expert panel assessment by three liver surgeons and three interventional radiologists took place to validate the primary outcome. The expert panellists were masked for local treatment decisions. Before the central expert panel evaluation, three independent abdominal radiologists retrospectively assessed the contrast-enhanced CT and liver contrast-enhanced MRI scans of all patients. More details on the expert panel assessment are reported in the appendix (pp 2–3).

Outcomes

The primary outcome was a change in local therapy plan on the basis of liver contrast-enhanced MRI findings in the intention-to-image population. Change in local therapy

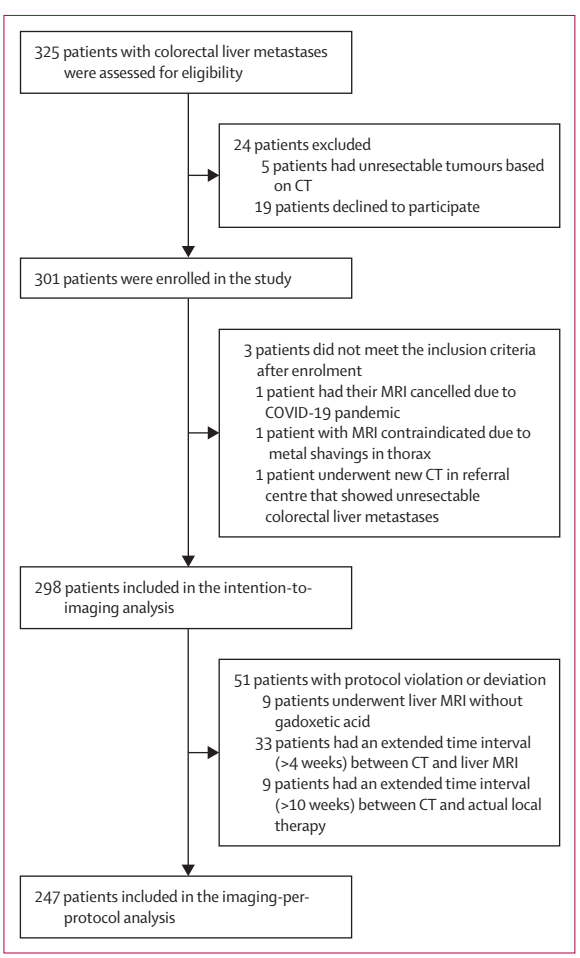

Figure 1: **Trial profile**

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See **Online** for appendix

was defined as any change in surgery or thermal ablation, including more extensive or less extensive surgery, an increase or decrease in the number of ablation zones, a change from surgery to ablation or ablation to surgery, addition of ablation to surgery, and cancellation of local therapy. The local therapy plan proposed by the multidisciplinary team meeting on the basis of contrast-enhanced CT only was compared with the local therapy plan based on both contrast-enhanced CT and liver contrast-enhanced MRI. Additionally, an imaging-per-protocol analysis was performed. Per protocol, only clinically significant colorectal liver metastases were defined as lesions that could lead to change of local therapy plan.[18] We report the findings as change of local therapy plan because this is a common term in daily practice.

Prespecified secondary outcomes were an evaluation of change in local therapy plan by a central, blinded, independent expert panel; change of pre-interventional local treatment plan between liver MRI findings and the actual local treatment; the use of contrast-enhanced intraoperative ultrasound, and recurrence of colorectal liver metastases during follow-up. Recurrence was defined as the appearance of new colorectal liver metastases during follow-up that were not seen before on imaging or during local therapy. They were assessed using different imaging modalities such as CT, MRI, and ultrasound. Within the current study, we considered follow-up and, if available, histopathology reports as combined reference standard. We explored the feasibility of developing a data-driven and theory-driven prediction model to estimate which patients should not undergo a liver contrast-enhanced MRI in the diagnostic testing (appendix pp 5–6).

All outcomes were assessed in all participants with available data.

Statistical analysis

Categorical variables and dichotomous data were reported as absolute values and percentages. Continuous, not normally distributed variables were expressed as median (IQR). Variables with normal distribution were reported as mean (SD). The main analysis of the CAMINO study was done according to the intention-to-image principle. The intention-to-image analysis included all CAMINO study participants who fulfilled the inclusion criteria and underwent the study procedure (ie, CT followed by MRI), regardless of any study protocol violation, such as an extended time

	All patients (n=298)
Age, years	66·3 (58·2–74·5)
Sex	
Male	177 (59%)
Female	121 (41%)
BMI, kg/m²	25·5 (23·0–28·4)
WHO performance status	
Grade 0	186/295 (63%)
Grade 1	104/295 (35%)
Grade 2	5/295 (2%)
Grade 3	0
Grade 4	0
Liver cirrhosis	0
Hepatic steatosis on contrast-enhanced CT	20 (7%)
Hepatic steatosis on liver contrast-enhanced MRI	47 (16%)
Site of primary colorectal carcinoma	
Coecum	24/296 (8%)
Ascending colon	32/296 (11%)
Transverse colon	14/296 (5%)
Descending colon	21/296 (7%)
Sigmoid colon	82/296 (28%)
Rectosigmoid	26/296 (9%)
Rectum	97/296 (33%)
Previous resection primary colorectal carcinoma	220 (74%)
T-stage of primary colorectal carcinoma	
1–2	44/281 (16%)
3–4	237/281 (84%)
Lymph node-positive primary colorectal carcinoma	201/284 (71%)
Carcinoembryonic antigen value, µg/L	36·2 (94·5)
Previous liver surgery for colorectal liver metastases	53 (18%)
Synchronous colorectal liver metastases	158/292 (54%)
Type of colorectal liver metastases	
Primary	250/297 (84%)
Recurrence	38 (13%)
Locoregional recurrence after previous local therapy	9 (3%)
Fong clinical risk score	2 (2–3)
Systemic therapy	
Pre-interventional systemic therapy	117/293 (40%)
Neoadjuvant systemic therapy	76/289 (26%)
Induction systemic therapy	37/289 (13%)
Time interval between contrast-enhanced CT and contrast-enhanced MRI, days	14 (6–22)
Time interval contrast-enhanced CT and local therapy, days	44 (34–53)
MRI contrast agent	
Gadoxetic acid	289 (97%)
Gadobutrol	3 (1%)
Gadoterate meglumine	3 (1%)
No contrast agent used	3 (1%)
Size of largest lesion on contrast-enhanced CT, mm	22·0 (13·5–32·0)
Number of lesions on contrast-enhanced CT	2 (1–3)

Data are n (%), mean (SD), or median (IQR). Fong clinical risk score indicates a clinical risk score to predict risk of early recurrence after liver resection. It consists of five clinical criteria including lymph node status, carcinoembryonic antigen value, disease-free interval, and size and number of liver metastases.

***Table 1*: Baseline characteristics of the intention-to-image population**

interval of more than 4 weeks between contrast-enhanced CT and liver contrast-enhanced MRI or liver contrast-enhanced MRI performed with another contrast agent than gadoxetic acid. We calculated the number of patients with additional findings on liver contrast-enhanced MRI not seen on contrast-enhanced CT leading to change of the local treatment plan, relative to the total number of patients. A 95% CI was calculated according to the Wilson score interval. The imaging-per-protocol analysis included all participants who underwent study procedures per study protocol. The incremental accuracy in the imaging-per-protocol analysis was calculated as the number of participants with additional findings on liver contrast-enhanced MRI not seen on contrast-enhanced CT leading to change of the local treatment plan, relative to the total number of included patients.

The expected change in local treatment plan was based on the combination of available literature and clinical experience. Anticipating a 10% proportion change, the 95% CI would extend from 7% to 14% with the inclusion of 298 patients.

For the primary outcome we performed predefined subgroup analyses: patients who did or did not receive preoperative systemic therapy, patients who did or did not undergo [^{18}F]fluorodeoxyglucose ([^{18}F]FDG)-PET-CT, and stratification based on the number of colorectal liver metastases lesions on contrast-enhanced CT.

A post-hoc rudimentary cost-effectiveness analysis was performed from a hospital perspective, addressing imaging, local treatments, and inpatient stay as major cost components (appendix pp 3–4).

Other post-hoc exploratory analyses were done to assess the effect of liver contrast-enhanced MRI in patients with steatosis; differences in extent between the actual local treatment and the local treatment plan based on liver contrast-enhanced MRI in patients who received and did not receive pre-interventional systemic therapy using a χ^2 test; and the extent of centre-effects by stratifying the primary endpoint data per centre and comparing the proportion of patients with a change in local treatment plan using a χ^2 test.

For statistical significance, a threshold of $p<0{\cdot}05$ was used. More details on the statistical analysis and the regression analysis of parameters, including the feasibility of developing both a data-driven and theory-driven prediction model to estimate which patients should not undergo a liver contrast-enhanced MRI in the diagnostic investigation, are described in the appendix (pp 4–6). Statistical analyses were done with IBM SPSS Statistics for Windows (version 25.0). The study was registered in the Netherlands Trial Register (NL8039).

Role of the funding source

The funders of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Between Dec 17, 2019, and July 31, 2021, 325 patients with colorectal liver metastases were assessed for eligibility. 24 patients were excluded due to unresectable tumours or declining to participate and 301 were enrolled in the study. 298 patients met the inclusion criteria and were included in the intention-to-image analysis and of these, 247 were included in the imaging-per-protocol analysis (figure 1). Baseline characteristics are presented in table 1; data on race or ethnicity were not collected. Details on pre-interventional systemic therapy are presented in the appendix (p 17). The median time interval between the cessation of pre-interventional systemic therapy and imaging was 11 days (IQR 6·25–21·75) for contrast-enhanced CT and 16 days (IQR 10·00–32·75) for contrast-enhanced MRI. Systemic treatment was still ongoing in 31 patients when contrast-enhanced CT was done and in 15 patients when contrast-enhanced MRI was done.

All participants could be included in the analysis as none had missing data for the primary outcome. The primary outcome of change in local treatment plan on the basis of liver contrast-enhanced MRI was observed in 92 (31% [95% CI 26–36]) of 298 participants (table 2). 40 (13%) of 298 patients needed more extensive local therapy, 11 (4%) needed less extensive local therapy. In 34 (11%) patients the indication for curative-intent local therapy was revoked after liver contrast-enhanced MRI,

	All patients (n=298)
No change in local treatment plan	206 (69%)
Change in local treatment plan	92 (31%)
More extensive local therapy	40 (13%)
More extensive local therapy (minor to minor)	32 (11%)
More extensive local therapy (minor to major)	8 (3%)
Less extensive local therapy	11 (4%)
Less extensive local therapy (minor to minor)	10 (3%)
Less extensive local therapy (major to minor)	1 (<1%)
No local treatment	34 (11%)
From local therapy to induction systemic therapy	15 (5%)
From local therapy to palliative systemic therapy	11 (4%)
From local therapy to no local therapy due to benign lesions on contrast-enhanced MRI	8 (3%)
Other	7 (2%)
From resection to selective internal radiotherapy	1 (<1%)
From resection to liver transplantation due to irresectability	1 (<1%)
From thermal ablation to follow-up of colorectal liver metastases	1 (<1%)
From one-stage to two-stage hepatectomy	1 (<1%)
From resection to thermal ablation (same localisation)	2 (1%)
From resection to resection of a different segment than initially determined based on contrast-enhanced CT	1 (<1%)

Data are n (%).

Table 2: **Primary outcome of changes in local treatment plan of the intention-to-image population**

including eight (3%) of 298 patients in which suspected colorectal liver metastases were found to be benign on liver contrast-enhanced MRI and 15 (5%) patients who were initially amenable for local treatment based on contrast-enhanced CT, but contrast-enhanced MRI showed potential benefit from induction systemic therapy. Per participating centre, a post-hoc analysis showed that the proportion of patients with a change in the local treatment plan ranged from 14% (95% CI 3–35) to 57% (18–90; p=0·24; appendix p 17).

The central, blinded, expert panel evaluated 297 of the 298 patients; one (<1%) of 298 patients was not evaluated due to inadequate contrast-enhanced CT. A change in local treatment plan based on liver contrast-enhanced MRI was indicated in 101 of 297 patients (34% [95% CI 29–40]). This included 79 minor and 22 major modifications. In 66 (22%) of 298 patients, both the expert panel and the multidisciplinary team in the participating centres agreed that a change in the local treatment plan based on liver contrast-enhanced MRI was necessary. In 35 (12%) of 298 patients, the expert panel recommended a change in local treatment based on liver contrast-enhanced MRI, while the multidisciplinary team determined that no change was needed. In 26 (9%) of 298 patients, the multidisciplinary team in the participating centres recommended a change in local treatment, while the expert panel concluded that no change in the local treatment plan was necessary.

Of the 261 patients with an indication for local treatment, as assessed by each participating centre on the basis of liver contrast-enhanced MRI, 252 (97%) underwent local treatment, including 163 (62%) patients who underwent resection, 34 (13%) patients who underwent thermal ablation, and 55 (21%) patients who underwent a combination of resection and intra-operative thermal ablation. In four (2%) of 261 patients, exploratory surgery without resection was done (three for advanced disease and one for extensive adhesions). In five (2%) of 261 patients, the local treatment plan was cancelled due to disease progression.

Intraoperative ultrasound was performed in 204 (92%) of 223 patients who underwent surgery and revealed additional lesions in nine (4%) patients (appendix p 18).

	Univariable analysis odds ratio (95% CI)	p value
Age	1·02 (0·99–1·05)	0·062
Sex		
Female	1 (ref)	..
Male	1·17 (0·71–1·93)	0·55
BMI	1·04 (0·98–1·10)	0·14
WHO performance status		
Grade 0	1 (ref)	..
Grade 1	0·88 (0·52–1·49)	0·62
Grade 2	3·39 (0·55–20·87)	0·19
Grade 3	..	..
Grade 4	..	..
Hepatic steatosis on contrast-enhanced CT		
No	1 (ref)	..
Yes	1·22 (0·47–3·17)	0·68
Site of colorectal carcinoma		
Coecum	1 (ref)	..
Ascending colon	1·96 (0·52–7·34)	0·32
Transverse colon	5·00 (1·12–22·41)	0·035
Descending colon	1·18 (0·26–5·43)	0·84
Sigmoid colon	2·74 (0·85–8·77)	0·090
Rectosigmoid	2·65 (0·69–10·15)	0·16
Rectum	2·24 (0·70–7·12)	0·17
Previous resection primary colorectal carcinoma		
No	1 (ref)	..
Yes	0·43 (0·25–0·74)	0·0020
T-stage of primary colorectal carcinoma		
1–2	1 (ref)	..
3–4	1·34 (0·64–2·79)	0·44
N classification of primary colorectal carcinoma		
0	1 (ref)	..
≥1	0·96 (0·55–1·69)	0·90
Carcinoembryonic antigen value	1·00 (0·99–1·00)	0·98
(Continued from previous column)		
Previous liver surgery for colorectal liver metastases		
No	1 (ref)	..
Yes	0·77 (0·39–1·50)	0·44
Time of diagnosis of colorectal liver metastases		
Metachronous	1 (ref)	..
Synchronous	2·12 (1·27–3·56)	0·0040
Type of colorectal liver metastases		
Primary	1 (ref)	..
Recurrence	0·92 (0·43–1·94)	0·82
Locoregional recurrence after previous local therapy	1·12 (0·27–4·61)	0·87
Disease-free survival between primary colorectal carcinoma and first colorectal liver metastases within 12 months		
No	1 (ref)	..
Yes	1·74 (0·98–3·08)	0·060
Size of largest lesion	0·96 (0·94–0·98)	0·0003
Pre-interventional systemic therapy		
No systemic therapy	1 (ref)	..
Neoadjuvant systemic therapy	1·10 (0·62–1·97)	0·747
Induction systemic therapy	0·88 (0·40–1·99)	0·76
Number of lesions	1·26 (1·12–1·42)	0·0001
Distribution		
Unilobar	1 (ref)	..
Bilobar	2·11 (1·26–3·53)	0·0040

Table 3: **Univariable analysis of parameters associated with change in local treatment plan based on liver contrast-enhanced magnetic resonance imaging**

Six of nine patients who had additional lesions underwent surgical resection to remove these lesions, in whom histopathology confirmed the presence of colorectal liver metastases. Only one centre used contrast-enhanced intraoperative ultrasound in specific settings (eg, if tumours visible at MRI could not be found intra-operatively), all others used intraoperative ultrasound without contrast medium.

Of the 252 (85%) of 298 patients who underwent local treatment, the extent of actual local treatment changed intra-operatively in 68 patients (27%) compared with the local treatment plan based on liver contrast-enhanced MRI. The details of these changes are described in the appendix (p 19). Within the group of patients with a change in pre-interventional local treatment plan on the basis of liver contrast-enhanced MRI findings, the type of local treatment plan (ie, local therapy or no local therapy) based on liver contrast-enhanced MRI was similar to the type of actual local treatment in 91 (99%) of 92 patients. In 55 (60%) of 92 patients, the intended treatment plan was local therapy; the extent of actual local treatment was changed in 20 (36%) of the 55 patients during local therapy. A post-hoc sub-analysis was conducted to determine the differences in extent between the actual local treatment and the local treatment plan based on liver contrast-enhanced MRI in patients who received and did not receive pre-interventional systemic therapy. A significant increase in procedural changes was observed among patients who received pre-interventional systemic therapy compared with those who did not (39 [33·3%] of 117 *vs* 38 [21·6%] of 176; p=0·049).

As of data cutoff (Jan 14, 2020), the median follow-up of the 40 (13%) of 298 patients with more extensive local treatment based on liver contrast-enhanced MRI was 7·0 months (IQR 6·0–8·0) and recurrence was observed in 13 (33%) of 40 patients. Median follow-up of the eight (3%) of 298 patients who were withdrawn from local treatment due to benign lesions on liver contrast-enhanced MRI was 21·0 months (IQR 17·5–24·0). None of them had local recurrence on abdominal contrast-enhanced CT (n=5), abdominal ultrasound (n=2), or liver contrast enhanced MRI (n=1) during follow-up. Median follow-up of the 15 (5%) of 298 patients who received induction systemic therapy based on liver contrast enhanced MRI was 7·0 months (IQR 6·0–9·0). During follow-up of these patients, six (40%) could be safely resected, five (33%) had complete response, and four (27%) had disease progression. Two (13%) of the 15 patients died due to the disease progression and 13 (87%) were still alive at a median follow-up of 7 months. Results of the prespecified subgroup analyses are provided in the appendix (pp 19–20). A post-hoc analysis showed no significant difference between change in local treatment plan in patients with and without hepatic steatosis on CT (35·0% *vs* 30·6%; p=0·68; appendix p 20).

Results of univariable analysis of predictors of change are shown in table 3. We built a multivariable logistic regression model with the following predictors: age, BMI, WHO performance status, site of primary colorectal carcinoma, previous resection of primary colorectal carcinoma, time of diagnosis of colorectal liver metastases, disease free survival between primary colorectal cancer and first colorectal cancer metastases within 12 months, size of largest lesion on contrast-enhanced CT, number of lesions on contrast-enhanced CT, and distribution of lesions (appendix pp 5–6). We analysed the distribution of calculated probabilities and observed that only a small subgroup of patients had a probability of 5% or less for change in local treatment plan based on liver contrast-enhanced MRI (figure 2). We therefore decided that development of a data-driven prediction model would not be helpful in daily clinical practice. A calibration plot of the proposed multivariable prediction model and the results of the theory-driven prediction model are shown in the appendix (pp 7–8).

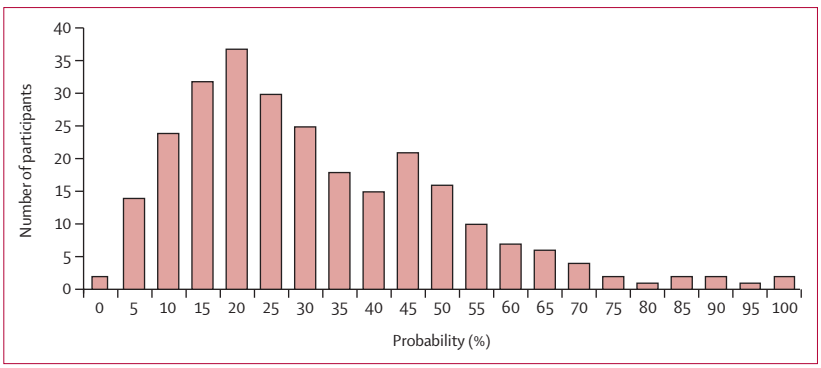

Figure 2: **Calculated probabilities of changes in local treatment plan based on liver contrast-enhanced MRI, intention-to-image population**

The post-hoc cost effectiveness decision tree analysis is depicted in figure 3. The pre-interventional treatment plan changed in 92 (31%) of 298 patients. Local treatment was not performed in 34 (11%) of these 298 patients, while changes were made in the local treatment plan of 58 (19%) patients. Because of insufficient information on the extent to which intraoperative findings allowed surgeons to proceed as planned, we decided to apply a standard unit cost of local treatment and perform a rudimentary analysis. The costs are expressed in Euros (base year 2022) and represent the Dutch context. The decision tree analysis showed a provisional net saving in costs of €128 191 or €430 per patient.

Discussion

This study showed that liver contrast-enhanced MRI changed the local treatment plan in about a third of patients. In one in ten patients, local treatment was withheld, including a small subset of patients in whom liver contrast-enhanced MRI identified the presumed colorectal liver metastases as benign lesions. Subgroups where a liver contrast-enhanced MRI clearly would have no clinical effect in the staging of colorectal cancer metastases could not be identified. These findings

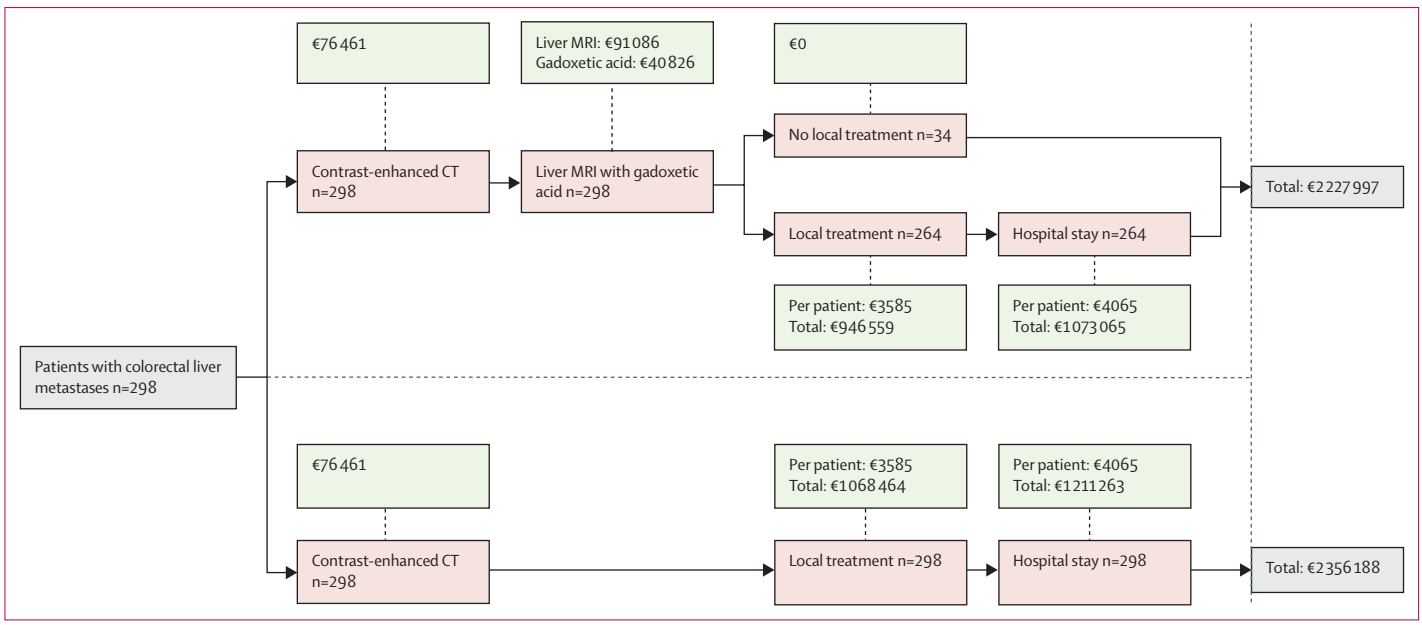

Figure 3: **Decision tree cost-effectiveness analysis**

suggest that liver contrast-enhanced MRI should be considered in the routine diagnostic work-up of patients with primary and recurrent colorectal liver metastases amenable for local therapy.

There was a discrepancy of 27% between the extent of the actual local treatment and the intended local treatment plan based on liver contrast-enhanced MRI. This percentage is in line with the literature and might be explained by the superior performance of intraoperative ultrasound leading to changes in management in 12% to 24% of patients.[19–21] In the present study, intraoperative ultrasound revealed additional lesions in 4% of the patients during surgery, leading to modifications of the local treatment plan. Based on the existing literature and current results, intraoperative ultrasound remains an important adjunct of preoperative imaging.

Advanced CT techniques such as spectral CT have a better diagnostic accuracy than do conventional contrast-enhanced CT scans.[22,23] To date, only one single-centre study with 20 patients compared the diagnostic performance of spectral and conventional contrast-enhanced CT for colorectal liver metastases, showing a higher diagnostic accuracy for spectral CT.[24] Whether these developments could affect the role of CT in colorectal liver metastases has to be investigated, with consideration of further developments in MRI. Liver contrast-enhanced MRI as first-line imaging is hampered by the need for chest CT scans for staging.

The median time interval between contrast-enhanced CT and liver contrast-enhanced MRI was 14 days (IQR 6–22), which might prove too short for some health-care settings. The increased use of MRI might have a negative effect on the waiting time. However, the routine use of MRI might also have advantages because centres could allocate more time slots for MRI within their MRI capacity or implement a fast-track CT-followed-by-MRI pathway. Studies on abbreviated imaging protocols for liver contrast-enhanced MRI have shown non-inferiority compared with typical liver contrast-enhanced MRI protocols and therefore potential increases in time efficiency.[25–27] Studies investigating the effect of abbreviated liver contrast-enhanced MRI on surgical management might be the focus of future research.

Upon assessment by the central, blinded expert panel, liver contrast-enhanced MRI altered the local treatment plan in 34% of patients, which aligns with our primary outcome in the participating centres. It is crucial to understand that decisions made by the expert panel and the multidisciplinary team in the participating centres each have their unique advantages and limitations. The expert panel's decisions provide an objective assessment in a controlled, centralised setting with specific expertise. By contrast, the decisions of the multidisciplinary team in participating centres are guided by the patient's entire clinical context. Although a cluster randomised controlled trial design could potentially overcome some of these limitations, it was deemed unfeasible and ethically challenging due to the established use of liver contrast-enhanced MRI in daily clinical practice at several hospitals before the start of the CAMINO trial.

A rudimentary decision tree analysis of the health economic consequences showed that about €430 could be saved per patient, mostly due to foregone local treatments in 11% of patients. This was a post-hoc analysis rather than a proper cost-effective analysis, which was not in the scope or remit of this study.

The results of this study should be interpreted considering some limitations. First, our primary outcome

of change in local treatment plan could not be masked for physicians. This might potentially introduce bias. However, our study was designed pragmatically to reflect the clinical reality in which multidisciplinary team members, including surgeons and interventional radiologists, decide on a local treatment plan on the basis of liver contrast-enhanced MRI while also having knowledge about the contrast-enhanced CT findings. It is important to note that awareness of the study might have influenced physicians and encouraged them to fine-tune their local treatment plans on the basis of contrast-enhanced CT or to scrutinise for differences between contrast-enhanced CT and liver contrast-enhanced MRI. However, we believe that these effects probably balanced each other within the study. Second, contrast-enhanced CT scan and contrast-enhanced MRI scan protocols were not completely standardised between participating centres. This might have allowed some differences in the interpretation of findings. However, participating centres complied with the minimal requirements according to the imaging protocols from the Radiological Society of the Netherlands. Third, despite evidence supporting the superiority of the combination of gadoxetic acid-enhanced liver MRI and diffusion-weighted imaging compared with extracellular contrast media and non-diffusion-weighted imaging liver MRI,[11,28] not all centres use this combination as standard liver MRI protocol in the detection of colorectal liver metastases in their daily practice. Further studies will have to assess the effect of liver MRI without contrast and without diffusion-weighted imaging in this setting. Fourth, the contrast-enhanced CT and liver contrast-enhanced MRI of patients were not routinely evaluated by one radiologist in the participating centres. Similarly, multidisciplinary team members, including surgeons and interventional radiologists, might vary over meetings. Additionally, considering this variability, we installed a central, blinded independent expert panel to confirm our findings. Fifth, because the CAMINO study had a pragmatic design following daily clinical practice, histopathology reviews were not standardised. Histopathological examination as a reference standard could also not be used in many instances, as the changes in local treatment plan mainly included less extensive surgery or changes from local therapy to no local treatment. No histological material was obtained from these patients. Furthermore, more extensive local treatment might include additional ablation without any histological material. Lesions were thus considered true positives on the basis of their radiological features. Sixth, the current study aimed to improve characterisation of the disease extent that would benefit the patient by optimising their treatment regimen, rather than measure actual patient outcomes such as disease-free survival and overall survival.

The strength of this study lies mostly in its pragmatic prospective, multicentre design, including patients from four countries, with standardised use of contrast-enhanced MRI and an expert panel review of all patients to validate the findings of the individual centres. Our findings suggest that liver contrast-enhanced MRI should be considered in the routine diagnostic investigation of patients with primary and recurrent colorectal liver metastases amenable for local therapy based on contrast-enhanced CT.

Contributors

BG, PMB, CV, MGB, and JS were involved in the study conceptualisation and design. All authors were involved in data acquisition. BG and JPS accessed and verified the data. BG, JPS, MGWD, PMB, CV, MGB, and JS carried out the analyses and interpretation of data. CV, MGB, and JS provided supervision during concenptualisation, design, data acquisition, data analyses, data interpretation, drafting of the manuscript, and final approval. BG, CV, MGB, and JS wrote the original manuscript draft. All authors revised the manuscript critically for important intellectual content and provided final approval of the version to be published. All authors had access to the underlying data that were used in the present study and had final responsibility for the decision to submit for publication.

Declaration of interests

BE received honoraria from Medtronic for lectures. KH has a leadership role in the Dutch Colorectal Cancer group. DJL received honoraria from Intuitive surgical. MMa received support for travel to attend the following courses where she gave lectures: ECIO 2023, ESGAR Liver Imaging workshop, and Alimentary tract cancer course New York 2023. MMe received grants from Medtronic–Covidien, Johnson & Johnson, Immunophotonics, and Angiodynamics. MMe also received consulting fees from Angiodynamics and Medtronic–Covidien; honoraria from Medtronic–Covidien, Johnson & Johnson, and Angiodynamics; and support for attending meetings from Angiodynamics. MMe is participating in the Data Safety and Monitoring Board of the Combining Hepatic Percutaneous Perfusion with Ipilimumab plus Nivolumab in advanced uveal melanoma trial and had leadership or fiduciary roles in the Society of Interventional Oncology, CIRSE & ECIO, and CVIR. ÅAF received honoraria from Bayer AG, Olympus Healthcare, and Siemens Healthineers. JS received funding from the Dutch Cancer Society (grant number 11916) and is president-elect of the European Society of Gastrointestinal and Abdominal Radiology. All other authors declare no competing interests.

Data sharing

Data supporting this work and additional related documents (ie, study protocol and informed consent forms) are available for qualified researchers upon reasonable request. Data will include individual participant data that underlie the results reported in this Article, after de-identification (text, tables, figures, and appendices). Requests could be made following publication and ending 5 years after publication. Requests to access data should be made to the corresponding author.

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