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Multi-center, randomised comparison study to evaluate outcomes and resource needs of imaging and treatment following Gd-EOBDTPA-enhanced MRI of the liver in comparison to extracellular contrast media (ECCM)-enhanced MRI and contrast-enhanced multidetector computed tomography (MDCT) in patients with a history of colorectal cancer and known or suspected metachronous liver metastases: The VALUE study


Purpose: To compare gadoxetic-acid-enhanced MRI (Gd-EOB-DTPA-MRI), MRI with extracellular contrast media (ECCM-MRI) and contrast-enhanced MDCT (CE-MDCT) as initial diagnostic modalities in the local work-up of patients with colorectal liver metastases.

Methods and Materials: 34 study centres included 342 patients with suspected liver metastases from 10/2008 to 09/2010. The initial imaging technique to be used was randomised. The primary variable was the proportion of patients for whom further imaging was required after initial imaging. For this decision a consensus between a liver surgeon and radiologist on-site was reached. Secondary variables included confidence, diagnostic efficacy parameters and impact on the surgical plan in the subgroup of patients with histopathology and/or intraoperative ultrasound.

Results: Further imaging was required in 0/118 (0%), 19/112 (17%) and 44/112 (39%) cases after Gd-EOB-DTPA-MRI, ECCM-MRI and CE-MDCT, respectively (p < 0.0001). Diagnostic confidence was high/very high in 98.3%, 85.7% and 65.2%, respectively. In the subgroup of patients who underwent surgery (112/342) sensitivity for detection of metastases was 93.8%, 89.4% and 84.1% for Gd-EOB-DTPA-MRI, ECCM-MRI and CE-MDCT, respectively. Surgical plan was changed and surgery time increased in 12.8%, 16% and 29.4% of patients after Gd-EOB-DTPA-MRI, ECCM-MRI and CE-MDCT, respectively. Gd-EOB-DTPA-MRI as second imaging avoided unnecessary surgeries in 4/24 patients (16.6%) scheduled for surgery.

Conclusion: The results show superiority of Gd-EOB-DTPA-MRI over CE-MDCT and ECCM-MRI for evaluating patients for liver surgery. Patients randomised for Gd-EOB-DTPA-MRI as initial staging strategy needed no further imaging to assess operability with implications for work-flow and costs. The comparison of diagnostic efficacy parameters demonstrates the diagnostic benefit of Gd-EOB-DTPA-MRI.

ECONOMIC EVALUATION OF PRIMOVIST VERSUS EXTRACELLULAR CONTRAST IN IMAGING OF LIVER METASTASES OF COLORECTAL ORIGIN

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OBJECTIVES: The main purpose of this study was to conduct an economic evaluation of Primovist enhanced MRI (PV-MRI) compared to extracellular contrast-media-enhanced MRI (ECC-MRI) in patients suffering from liver metastases of colorectal origin in Spain. METHODS: An analytic model previously implemented in three European countries (Germany, Italy and Sweden) was adapted in Spain to estimate all aggregated costs of both diagnosis options compared. Probabilities of needing further imaging and of needing surgical plans modification or confirmation were adjusted by Spanish clinical experts (surgeons and radiologists). Contrasts cost was estimated from PTR (weighting the different EECs prices for sales in Spain for this option), and tests (MRI and CT) and different surgery procedures (high or low risk, modification or confirmation of surgical plans, etc.) costs were extracted
from official fees of different Spanish Autonomous Communities (CCAAs).

**RESULTS:** PV-MRI was associated with a reduced need for extra imaging tests (6% vs. 9%). Taking into account the costs of diagnosis tests and surgery procedures (including modification of surgical plans during intervention), PV-MRI option was a cost-neutral strategy, with total costs similar to ECC-MRI (€576 vs. €578, PV-MRI vs ECC-MRI respectively). **CONCLUSIONS:** Additional costs associated with colorectal liver metastases diagnosis with PV-MRI regarding to ECC-MRI are offset by lower costs in intraoperative changes of the surgical plan and reductions in unnecessary surgery associated with the use of PV-MRI. Results from the previous study VALUE, which showed that no patient with PV required additional imaging tests as part of a Phase IV, confirm the results obtained in the present analysis (resulting in even slightly lower cost than the total cost of diagnosis using PV-MRI).