Intraoperative detection of colorectal cancer using a carcinoembryonic antigen-targeting near-infrared fluorescent agent (SGM-101): a pilot study

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Introduction

Tumour-targeted fluorescence imaging has the potential to revolutionize current practice of oncologic surgery by selectively highlighting malignant tissue during surgery, enabling radical tumour resections. Carcinoembryonic antigen (CEA) is overexpressed in the majority of colorectal cancers (CRC) and is a promising tumour-target for CRC imaging. The aim of this dose-escalating study was to determine tolerability of SGM-101 a fluorescent anti-CEA monoclonal antibody, and to investigate the feasibility to detect CRC with intraoperative fluorescence imaging (FI).

Methods

Patients with primary CRC or local recurrence or peritoneal metastases (PM) of CRC, with elevated or increasing serum CEA levels since diagnosis and scheduled for open or laparoscopic tumour resection, were included in this phase I/II multicenter trial. Two or four days prior to surgery, 5.0, 7.5 or 10 mg SGM-101 was administered intravenously to primary CRC patients to optimize the dose and time of FI. Accuracy of the technique was investigated in an expansion cohort of patients with recurrent CRC or with PM using the optimal dose.

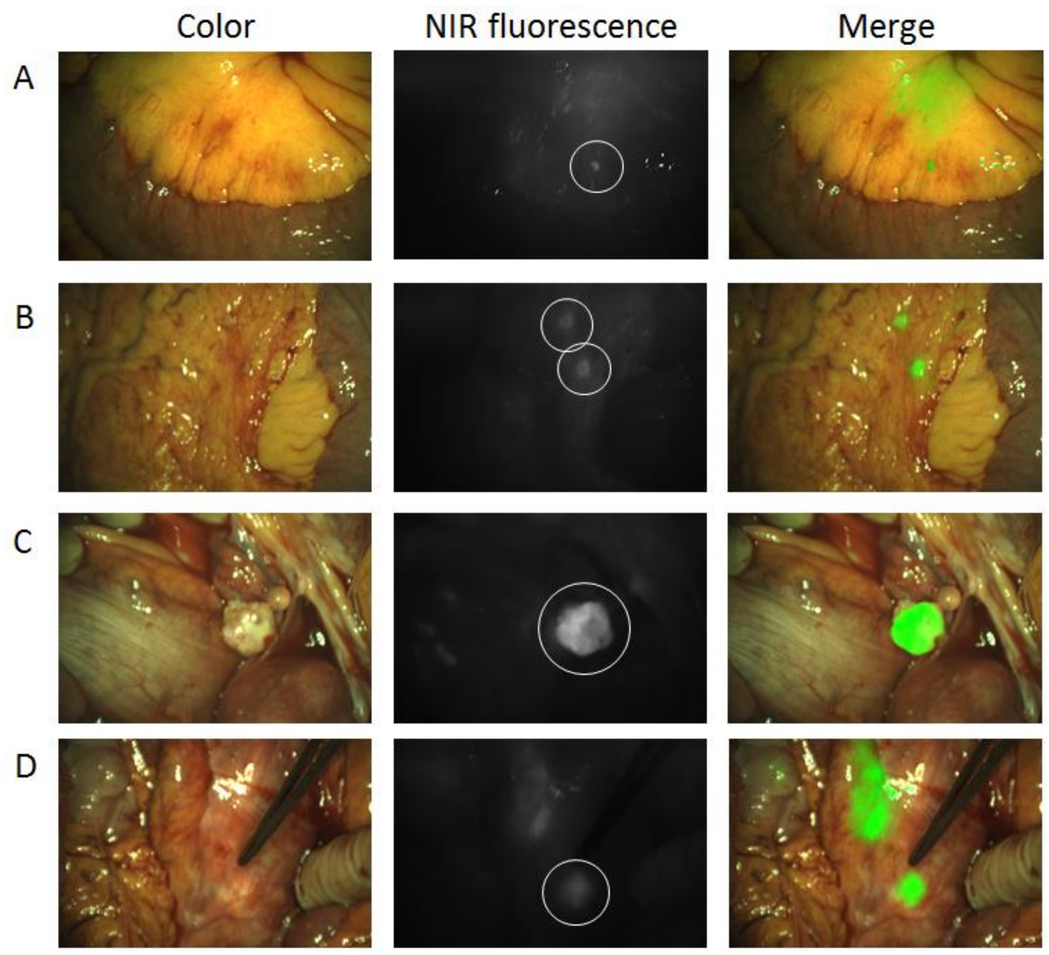
Results

Nine patients with primary and 17 with recurrence or PM of CRC were included. SGM-101 did not cause any treatment-related adverse events. A dose of 10 mg, administered 4 days prior to surgery, showed the highest tumour-to-background ratio. In the expansion cohort, 19 (43% of all lesions) additional malignant lesions were detected using fluorescence imaging, which changed the treatment strategy in 6/17 patients (32%). Sensitivity, specificity and accuracy of FI in the expansion cohort were 98%, 62% and 84%, respectively.

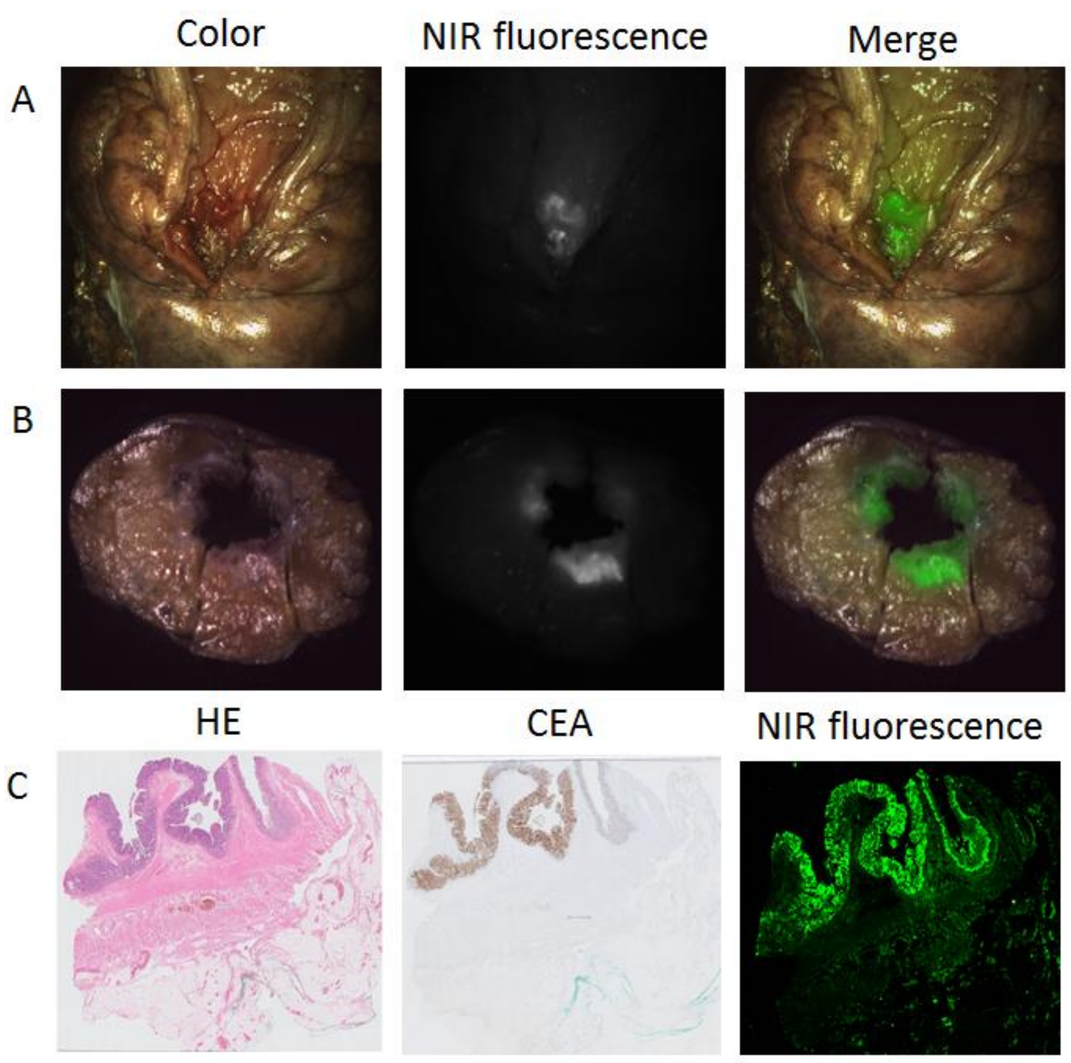
	Sensitivity	Specificity	Accuracy
Primary CRC	93% (13/14)	67% (4/6)	85% (17/20)
Recurrence or PM of CRC	98% (43/44)	62% (16/26)	84% (59/70)

Conclusion

This study presents the first clinical experience of CEA-targeted detection of CRC and demonstrates that SGM-101 is safe and can influence clinical decision-making during the surgical procedure in a substantial part of CRC patients.



*Intraoperative fluorescence detection of additional metastases; **a** bowel mesentery, **b** omentum, **c** right ovary and **d** retroperitoneal lymph nodes.*



*Ex vivo fluorescence imaging of a primary rectal cancer; **a** specimen, **b** corresponding tumour slice and **c** histopathological analysis.*

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