Image-guided surgery in patients with pancreatic cancer: first results of a clinical trial using SGM-101, a novel carcinoembryonic antigen-targeting, near-infrared fluorescent agent

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Introduction

Intraoperative differentiation between tumour and healthy tissue is often difficult in pancreatic ductal adenocarcinoma (PDAC) and this can lead to incomplete tumour removal. Near-infrared (NIR) fluorescence is a promising novel imaging technique that has the potential to improve intraoperative demarcation of PDAC and radical resection rates. We studied SGM-101, a novel, fluorescent-labelled antibody that targets carcinoembryonic antigen (CEA), which is abundantly expressed in PDAC. Our aim was to assess the tolerability and feasibility of intraoperative fluorescence tumour imaging using SGM-101 in patients undergoing a surgical exploration for pancreatic ductal adenocarcinoma.

Methods

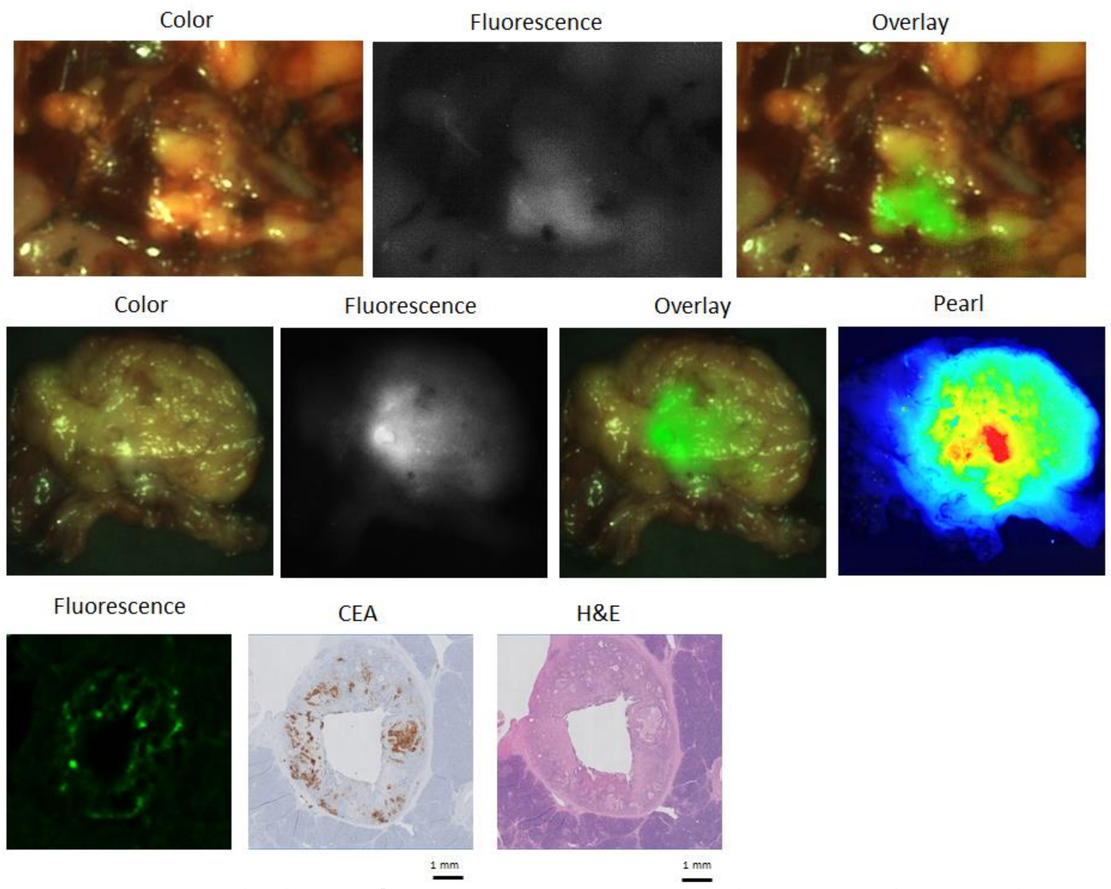
Twelve patients were injected intravenously with 5.0, 7.5 or 10 mg SGM-101 at least 48 hours prior to undergoing surgery. Tolerability assessment was performed at regular intervals after dosing. The surgical field was imaged using the Quest NIR imaging system. Concordance between fluorescence and tumour presence on histopathology was studied.

Results

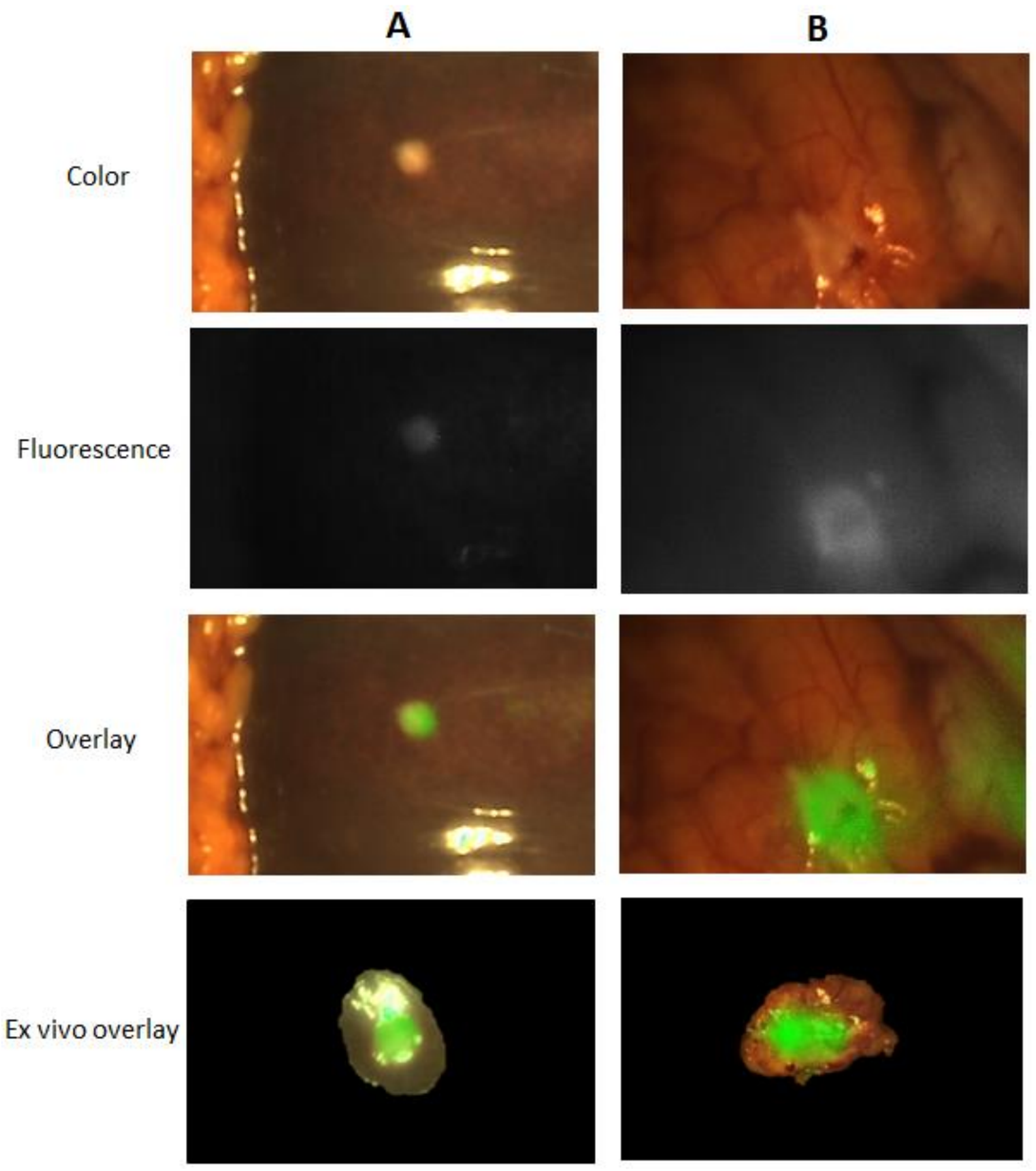
SGM-101 specifically accumulated in CEA-expressing primary tumours and peritoneal and liver metastases, allowing real-time intraoperative fluorescence imaging (Fig. 1). The mean tumour-to-background ratio (TBR) was 1.6 in primary tumours and 1.7 in metastatic lesions. Out of 21 lesions, only one false positive lesion was detected (CEA-expressing intraductal papillary mucinous neoplasm) and two false negative lesions were detected.

Conclusion

The use of a fluorescent-labelled anti-CEA antibody was safe and feasible for the intraoperative detection of both primary PDAC and metastases. While the current technique should be further improved to maximize TBR and sensitivity, our study demonstrates that intravenously injected SGM-101 is able to penetrate PDAC and allows intraoperative fluorescence imaging.



Fluorescence detection of a primary pancreatic tumour, intraoperative imaging (upper row), ex vivo imaging of slice (middle row) and histopathologic evaluation (lower row).



*Fluorescence detection of metastases of a pancreatic tumour; **a** peritoneal metastasis and **b** liver metastasis.*

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