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Risk of bowel obstruction in patients undergoing neoadjuvant chemotherapy for high-risk colon cancer: A nested case-control matched analysis of an international, multi-centre, randomised controlled trial (FOxTROT)

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Background

Global implementation of neoadjuvant chemotherapy (NAC) for colon cancer, informed by the FOxTROT trial, may increase risk of bowel obstruction. This study aims to inform patient selection for NAC.

Methods

A case-control study, nested within an international randomised controlled trial (FOxTROT. ClinicalTrials.gov: NCT00647530). Patients randomised to NAC that developed large bowel obstruction were included. Firstly, clinical outcomes were compared between patients receiving NAC in FOxTROT that did and did not develop obstruction. Secondly, obstructed patients (cases) were age- and sex-matched with patients that did not develop obstruction (controls) in a 1:3 ratio using random sampling. Bayesian conditional mixed-effects logistic regression modelling was used to explore clinical, radiological, and pathological features associated with obstruction. Absolute risk of obstruction based on the presence or absence of risk criteria was estimated for all patients receiving NAC.

Results

Of 1053 patients randomised in FOxTROT, 699 received NAC, of whom 30 (4.3%) developed obstruction. There was more open surgery (65.4% versus 38.0%, p=0.01) and a higher pR1 rate in obstructed patients (12.0% versus 3.8%, p=0.004), but otherwise comparable postoperative outcomes. In the case-control matched Bayesian model, two independent risk criteria were identified: (1) obstructing disease on endoscopy and/or being unable to pass through the tumour (adjusted odds ratio: 9.09, 95% credible interval: 2.34-39.66) and stricturing disease on radiology or endoscopy (OR: 7.18, 95% C.I.: 1.84-32.34). Three risk groups were defined according to the presence or absence of these criteria: 63.4% (443/698) of patients were at very low risk (<1%), 30.7% (214/698) at low risk (<10%), and 5.9% (41/698) at high risk (>10%).

Conclusions

Safe selection for NAC for colon cancer can be informed by using two features that are available before treatment initiation and identify a small number of patients with high risk of preoperative obstruction.

Clinical trial identification

NCT00647530.

Legal entity responsible for the study

Birmingham Clinical Trials Unit, University of Birmingham.

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Disclosure

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