

NICE Health Technology Appraisal The use of oxaliplatin and capecitabine for the adjuvant treatment of colorectal cancer

Introduction

The bowel cancer treatments under appraisal in this review reflect some of the exciting current developments in the adjuvant setting, i.e. after surgery: the use of combination chemotherapy (oxaliplatin, 5FU and leucovorin - FOLFOX) and of oral chemotherapy (capecitabine).

The availability and proven efficacy of these drugs and combinations of drugs is indicative of just how much the bowel cancer landscape has changed in recent years. After nearly 50 years of only one drug being available - 5FU - there is now a range of treatment options for patients to choose from, which significantly improve patients' five year survival times and more.

Colon Cancer Concern (CCC) believes that the significant benefits that these drugs provide in the adjuvant setting, both in monotherapy and combination, mean that they should be approved for use by NICE, in the same way that NICE is now proposing to make a range of advanced chemotherapy treatments available in first and second line treatment of metastatic colorectal cancer: a decision we warmly welcome.

We further believe that these drugs must be judged on their individual merits in this appraisal, not in competition with each other. They both have different benefits and it would be wrong to make a direct comparison between them. Below is our synopsis of these benefits, which, in our view, make a very convincing case for both drugs being made as widely available as possible.

Capecitabine

Colon Cancer Concern (CCC) played an important role in NICE's review of capecitabine in the metastatic setting in 2003, by submitting case studies for patients who had taken the treatment. In the published guidance, NICE publicly recognised the value of our submission in persuading them of the efficacy of the drug for metastatic patients. We are delighted to have the opportunity to contribute to this appraisal of the drug in the adjuvant setting.

Capecitabine is a significant drug for four main reasons: it offers patients proven treatment benefits; it helps to empower patients by virtue of being in tablet form; it frees up valuable NHS personnel and resources; and it represents a positive step forward in the relationship between patients and clinicians, helping to develop a climate of trust and partnership between them during the course of the patient pathway.

More/...

The results of the recent X-ACT trial show that capecitabine offers improved relapse free survival when compared to traditional bolus 5FU, and also a trend towards improved disease free survival and overall survival. In addition, because the drug is taken in tablet form, it means that patients on capecitabine use less hospital resources and staff time, needing fewer treatment related stays in NHS hospitals and fewer visits to receive intravenous drugs.

It was clear from our 2003 NICE submission that metastatic patients on capecitabine valued the opportunity to have greater control over their treatment pathways and felt empowered by the freedom it gave them. We are convinced that patients will benefit equally from the drug in the adjuvant setting.

A Patient's Experience of Capecitabine

██████████ The first indication that he was unwell came in June 1999 when he passed a great deal of blood. After he visited his GP, he was immediately referred to a consultant for further tests. In July of the same year he was diagnosed with colon cancer. He required immediate surgery to remove the tumour: a daunting prospect for a healthy man in his 40s.

After surgery in a private hospital, ██████████ was offered the opportunity to be involved in a trial with capecitabine, which allowed him the freedom to take the treatment at home. ██████████ had been very nervous about taking i.v. chemotherapy and was particularly pleased that by taking oral chemotherapy he was able to get on with leading a normal life and did not have to constantly visit the hospital for treatment.

██████████ returned to work in September 1999, a month after his surgery. He finished his course of treatment in January 2000 and has since received the all clear in his tests and scans.

We recommend that capecitabine be made widely available by NICE in the adjuvant setting.

FOLFOX (oxaliplatin/5FU/leucovorin)

CCC, as we have said, welcomes NICE's approval of the use of oxaliplatin (and irinotecan) in first line combination treatment in the metastatic setting, an outcome that we have campaigned long and hard for for several years and which will benefit significant numbers of patients.

We now turn our attention to the drug in the adjuvant setting, in the FOLFOX regimen. Oxaliplatin, like capecitabine, is a very important drug and its benefits in combination with 5-FU and leucovorin in the adjuvant setting are also highly significant.

More/...

As was shown in the recent four year data from the MOSAIC study, for every 100 colon cancer patients treated in the adjuvant setting, 39 will relapse after four years on 5FU/Leucovorin, while 30 patients - i.e. nine fewer in every 100 - will have relapsed after taking FOLFOX. This represents a relative risk reduction of 25%.

If you consider the actual numbers of adjuvant colon cancer patients who are suitable to take FOLFOX each year - approximately 8,000 people - this means that between 700 and 800 people will benefit from being on the FOLFOX regimen every year; patients who would not achieve this result without being treated with FOLFOX.

If you also consider that adjuvant colon cancer patients generally relapse during the first two years (unlike breast cancer patients who usually relapse around five years), then it's clear that the improvement that FOLFOX offers in four-year disease free survival over infusional 5FU is very significant for patients and those who care for them.

A Patient's Experience of FOLFOX

Bowel cancer patient [REDACTED], was given the FOLFOX regimen in 2000 as part of an international trial, following surgery to remove a large tumour in his bowel. The treatment was a success and now, five years on, he has been given the all-clear from the disease.

[REDACTED] remains convinced that the FOLFOX treatment combined with surgery has saved his life. "The doctor told me 'I'll give you 30 years because you've had state-of-the-art medication. It's the best available at the moment'."

We recommend that oxaliplatin in the FOLFOX regimen be made widely available by NICE in the adjuvant setting.

Conclusion

CCC remains dedicated to ensuring that all bowel cancer patients are given equal access to the treatments that are best for them. This includes the treatments in this appraisal, which offer a wide range of benefits, including improved five year plus survival, patient empowerment and significant savings in NHS costs, resources and personnel.

We are optimistic that these adjuvant chemotherapy treatments offer a first step towards finding a cure for colorectal cancer, by helping to rid patients of the disease after surgery. We strongly recommend that NICE takes this opportunity to help that aim become closer to reality, by making both of these treatments as widely available as possible.