

## [Advanced Colorectal Cancer](#)

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### **Safety of Chronic Low-Dose Capecitabine as Maintenance Therapy in GI Cancers**

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**Background:** Gastrointestinal (GI) cancers cause significant morbidity and mortality in the United States. The desire for less toxic regimens and improved quality of life have changed current treatment approaches to include chemotherapy-free intervals and reduced dosing, less toxic maintenance regimens. The oral fluoropyrimidine capecitabine may play a role in such therapeutic approaches. We conducted a retrospective review of the safety profile of chronic low-dose capecitabine as maintenance adjuvant therapy in patients with high-risk GI malignancies.

**Methods:** All patients had received previous standard chemotherapy regimens and had at least stable disease at the time of starting capecitabine maintenance therapy. Medical records were used to obtain data including dose of capecitabine, toxicities, and response to therapy where available. Patients were placed on a fixed capecitabine dose of 1,000 mg twice daily 5 days on, 2 days off. This was based on previous studies showing similar efficacy between what has now become traditional dosing of 2 weeks on, 1 week off and continuously dosed capecitabine.<sup>1</sup>

**Results:** Twenty-eight (28) patients were included in this retrospective study. Hand-foot syndrome was the most common side effect and was seen in 20 (71%) patients, but only one with grade 3. No other patients experienced any grade 3 toxicities. Fatigue, diarrhea, and anorexia occurred in 16 (57%), 6 (21%), and 4 (14%) patients, respectively. Toxicity experience did not differ significantly by age, gender, or body surface area (BSA). Mean corpuscular volume (MCV) was evaluated in 26 of 28 patients. MCV increased an average of 12.9% over baseline at the peak on treatment ( $P < .0001$ ). Peak MCV on treatment happened at a mean of 189.6 days. A total of 16 patients (62%) experienced MCV elevation defined as  $\geq 100$ .

**Conclusion:** Our study confirmed the previously reported adverse effect profile of capecitabine. By using lower doses of capecitabine in a continuous manner, we were able to limit grade 3 and 4 toxicities, with no withdrawal of therapy due to side effects. The observed elevation in MCV has also been reported in previous studies using standard-dose capecitabine.<sup>2-3</sup> Seeing the same MCV effect in our patient population argues that even at low doses of capecitabine there is still some biochemical effect, and that MCV change may be a possible biomarker. A prior study reported a statistically significant difference in rise of MCV between treatment responders and nonresponders.<sup>2</sup> Future prospective studies are needed to look at the efficacy of this regimen and the predictive role of MCV rise.

## References

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