Supplementary Results

Adherence to Treatment and Side Effects of Treatment

The average rate of adherence for taking celecoxib doses was 94.51% (SD: 5.5%), and 86.2% of patients maintained the requested drug intake calendars. Celecoxib serum levels were undetectable in all 29 patients at baseline prior to initiation of therapy. Average serum levels at 2, 4, and 6 months were 705.9 ng/ml, 864.3 ng/ml, and 677.9 ng/ml, respectively. Individual celecoxib levels for these time points are shown in supplementary Figure 1.

Celecoxib was well tolerated. Adverse events (AEs) were observed in 24 of the 32 patients (75%) who received celecoxib; however, the majority (75%) of these events (total number of events was 83) were grade 1 according to the National Cancer Institute Common Terminology Criteria for Adverse Events (version 3.0). Grade 2 AEs occurred in 9 patients (28%), and grade 3 AEs occurred in 2 (6%) patients. The 2 grade 3 AEs were abdominal pain judged to be unrelated to study drug (1 of these events occurred in a woman of reproductive age with an ovarian cyst). Gastrointestinal ARs accounted for 11 of the 19 grade 2 events [nausea (4), vomiting (3), eructation (1), abdominal pain (1), flatulence (1), and aphthous stomatitis (1)]. The other 7 grade 2 events were either unrelated to celecoxib [hot flashes (1), headache (1), knee pain (1), seizure (1), increased appetite (1), anemia existing prior to celecoxib intake (2), and rectal hematoma (1)] or were of unknown relation to celecoxib intake. No cardiac AEs were observed during the study.