**Purpose:** We evaluated the efficacy and toxicity of novel regimen of 5-fluorouracil (5FU) + calcium leucovorin (CaLV) and irinotecan in patients (pts) with metastatic colorectal cancer (mCRC).

**Patients and Methods:** From January 2006 to January 2008 twenty two consecutive pts (7F/15M) with mCRC were treated. Median age was 56 years (28 – 73), ECOG PS 0 (0 – 1), median number of metastatic sites was 2 (1 – 3). Nine pts were pretreated with 5FU based chemotherapy. Treatment schedule consisted of 5FU 450 mg/m², CaLV 20 mg/m², irinotecan 100 mg/m² weekly x 4 repeated every 5 weeks.

**Results:** Median number of cycles 4 (range: 1 – 12) were administered. Three partial responses were observed. Eight patients showed disease stabilisation for more than 6 months. Median time to progression was 5 months (95 % CI, 4 – 6 months), median overall survival was 17 months (95 % CI, 6 – 23 months). The main Gr 3–4 toxicity was neutropenia and hepatotoxicity which experienced 2 pts. Median relative dose intensity (RDI) of irinotecan was 1,08 (0,5 – 1,9) and RDI of 5FU was 0,98 (0,42 – 1,96).

**Conclusion:** This novel combination is active, safe and convenient in patients with metastatic colorectal cancer treated mainly on the out-patients base.

**Literature:**