Introduction: The CORRECT trial revealed the safety and efficacy of regorafenib for the treatment of patients with colorectal cancer including Japanese. Regorafenib was approved in Japan in March 2013. However, there are few studies exploring the efficacy of regorafenib in daily practice.

Methods: We analyzed 74 patients who received regorafenib from May 2013 in the multi-institutional retrospective study (HGCSG1401). This study was analyzed by CTCAE ver.4.0 for adverse event, RECIST criteria ver.1.1 for response rate, and Kaplan-Meier method for progression free survival and overall survival.

Results: Patients’ characteristics are as follows; male/female 43/31, median age 66 (range 29-87), ECOG Performance status (0/1/2/3) 11/51/11/1, KRAS Exon2 wild/mutant 41/32 (1 patient; KRAS Exon2 status was not tested). The initial starting dose was 160 mg (n = 57, 77.0%), 120mg (n = 16, 21.6%), and 80mg (n = 1, 1.4%) respectively. Dose reductions were required in 25 pts (33.8%); 21 patients (28.8%) discontinued therapy due to adverse events. The common grade 3 adverse events (≥10%) were palmar-plantar erythrodysesthesia syndrome (n = 20; 27.0%), hypertension (n = 18; 24.3%), proteinuria (n = 9; 14.8%; 13 patients, Urinary analysis was not tested), AST increased (n = 12; 16.2%), fatigue (n = 11; 14.9%), blood bilirubin increased (n = 10; 13.5%), and platelet count decreased (n = 8; 10.8%). Response rate (RR) and disease control rate (DCR) were 1.4% and 29.0%, respectively. Median progression-free survival (PFS) and median survival time (MST) were 2.0 and 5.4 months. In an analysis on relationship between ECOG PS (PS 0-1 vs. PS 2-3) and efficacy, DCR was 31.0% vs. 18.2% (p = 0.490), median PFS was 2.1 vs. 1.6 months (HR 2.200, p = 0.021), and MST was 6.3 vs. 2.3 months (HR 3.816, p < 0.001).

Conclusion: In the efficacy analysis, regorafenib showed similar efficacy to the previous report in patients with PS 0-1, but did not show efficacy in patients with PS 2-3. In adverse events, hypertension, proteinuria, liver dysfunction and platelet count decrease were expressed more frequently than previously reported. To aim to make the complete database of more than 150 cases, we continue to accumulate the clinical data from institutions participated in HGCSG1401.