Safety and efficacy analysis of bevacizumab combined chemotherapy for metastatic colorectal cancer patients (HGCSG0801)

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[Background]

The prolongation of the survival time of the colorectal cancer patients was shown by combination with cytotoxic agent and bevacizumab. Only the adverse event is reported by the post marketing surveillance as for the examination of the many cases in Japan though administering by approved in June, 2007, and effectiveness of many dairy practices is not reported.

[Methods]

The case who began administering bevacizumab in the participation facilities of this study between June, 2007 and October, 2008 was retrospectively analyzed. This study analized CTCAE ver.3.0 for adverse event, RECIST criteria ver.1.0 for response rate, and Kaplan-Meier method for progression free survival.

[Results]

212 patients from 17 institutions in Japan were administrated bevacizumab. Median age was 61years old(range 32-82). Patients characteristics ware male/female 111/101, colon cancer/rectal cancer 143/69, 1st line/2nd line/3rd line- 88/73/51, FOLFOX+Bevacizumab/FOLFIRI+Bevacizumab/other 104/73/55.

The adverse events with grade 3 or more related to Bevacizumab were gastrointestinal perforation(n=3), thrombosis(n=6), hypertension(n=30), gastrointestinal bleeding(n=2). Response rate was 60.2%/27.4%/9.8%(1st/2nd/3rd) and median progression free survival was 13.1months/7.5months/6.0months(1st/2nd/3rd). The follow-up survey is scheduled in August, 2009, and it reports on the latest safety and effectiveness.

[Conclusions]

After Bevacizumab had been approved in Japan, it analyzed it though small number of people were examples. It was safely administered, and an already reported, similar effectiveness was obtained even for the investigation mainly composed of a general hospital though a treatment-related death appeared. The follow-up survey concerning the continuation safety and effectiveness is scheduled to be done in the future.