RESULTS OF THE ONGOING NON-INTERVENTIONAL STUDY VALIDATE

QUALITY OF LIFE IN PATIENTS WITH RAS WILD-TYPE METASTATIC COLORECTAL CANCER RECEIVING 1ST-LINE PANITUMUMAB PLUS FOLFIRI OR FOLFOX

BACKGROUND

Panitumumab, a recombinant, fully human monoclonal anti-EGFR antibody, is approved, including but not limiting as first-line therapy in combination with FOLFIRI (5-FU + Folinic acid + Irinotecan) or FOLFOX (5-FU + Folinic acid + Oxaliplatin) for adult patients with RAS wild-type metastatic colorectal cancer (mCRC). The approval was based on several clinical trials.

Quality of life (QoL), however, has not been formally assessed in real-world so far and real-world data in general are scarce. To address the effect of panitumumab plus FOLFIRI or FOLFOX on QoL, patient-reported outcomes (PROs) were assessed in a large mCRC cohort. The present analysis shows first data on QoL during first-line treatment with panitumumab plus FOLFIRI or FOLFOX of the satellite project of VALIDATE.

METHODS

VALIDATE (NCT03499583) is an ongoing, multicenter, non-interventional study prospectively observing patients with RAS wild-type mCRC who are treated with first-line panitumumab plus FOLFIRI or FOLFOX, according to SAPSC. The primary focus of VALIDATE is to prospectively validate the four-factor mCRC prognostic score (MCRS) in a large real-world cohort of patients by evaluating several scales in three different risk groups (low/intermediate/high risk) on the EORTC. Mners. The satellite project was planned satellite project to access PROs on QoL using the validated questionnaires EORTC QOL-C30 and QLQCQ29 was established. Questionnaires were distributed at baseline and thereafter three-monthly during first-line treatment until end of treatment (EOT). Scores were calculated according to the respective EORTC manuals for each scale at single time points. Summary tables with descriptive statistics were used to display questionnaire results. A clinically relevant deterioration of a scale/single item was defined as a deterioration (increased symptoms) or decreased functionality of the median score by at least 10 points (clinical important difference, MID) compared to baseline at least 10 points (clinical important difference, MID) compared to baseline at least 10 points (clinical important difference, MID) compared to baseline at least 10 points (clinical important difference, MID).

RESULTS

In total, 613 patients were enrolled in VALIDATE. Of these, 366 patients consented to participate in the PRO module and 247 patients were evaluable i.e. filled out a questionnaire before start of treatment with panitumumab + FOLFIRI or FOLFOX (Figure 1). The questionnaire return rate per questionnaire timepoint is demonstrated in Table 1. Of all 366 patients who consented to participate in the PRO module, 247 patients were evaluable i.e. filled out a questionnaire before start of treatment with panitumumab + FOLFIRI or FOLFOX (Figure 1).

Overall, 64 functional and symptom scales of the QOL-C30 and QLQ-C29 did not show any clinically relevant changes during first-line panitumumab treatment as compared to baseline. In total, clinically relevant deteriorations were reported for two EORTC QOL-C30 functional scales (body image and social functioning), for two EORTC QOL-C30 symptom scale scores (fatigue and diarrhoea) and for six EORTC QOL-C29 scale scores (body image, dry mouth, dyspnoea, hair loss, pain, urinary symptoms). Scores that worsened during first-line panitumumab treatment were recovered (i.e., medians of the scale value was restored) or did not show any further deterioration although further course of treatment. QOL-C20 functional scales are exemplarily shown for social and physical functioning (Figure 3). QOL-C20 symptom scales are exemplarily shown for diarrhoea, fatigue, pain and nausea and vomiting (Figure 4). QOL-C29 is a self-report tool that is exemplary shown for dry skin, dry mouth, trouble with taste and weight (Figure 5).

CONCLUSION

The global health status remained stable over time without any clinically relevant deterioration during first-line treatment with panitumumab + FOLFIRI or FOLFOX. Symptom scales reflecting common reported side effects of panitumumab (e.g., skin reactions, diarrhea, nausea) also did not show any clinically relevant deteriorations during treatment, which is of greatest importance for patients diagnosed with advanced or metastatic disease.