Quality of life (QoL) in patients with metastatic breast cancer (MBC) treated with capcitabine: second interim analysis of the German non-interventional study (NIS)


ID-85

BACKGROUND AND AIM

Carcitabine is
• a commonly used treatment option for metastatic breast cancer (MBC)
• has proven efficacy in this setting as both monotherapy and in combination with other agents
• used as first-line treatment in and patients with pretreated metastatic disease.
• Improvements in quality of life (QoL) have also been reported with capcitabine treatment.1,2,3
• The purpose of this investigation was to evaluate QoL during capcitabine therapy as a part of routine MBC treatment in Germany in a non-interventional post-marketing surveillance study.
• We present the results of a pre-planned interim analysis of the study with up to 12 documented cycles of capcitabine treatment in 621 patients.

METHODS

Patients
• Pre- and peri-menopausal patients aged ≥18 years, with HER2-negative or HER2-positive locally advanced resectable or MBC were eligible for accrual. The accrual target is 750 patients.

Quality of life:
• The EORTC Quality of Life questionnaire QLQ-C30 [3.0] was used evaluated QoL.
• The QLQ-C30 incorporates 15 scales on
  • five functional scales:
  • physical; role; cognitive; emotional; social
  • a global health and QoL scale.
• (Note: Higher scores represent better functioning)
• nine symptom scales
• To evaluate patient satisfaction with the overall cancer treatment/side effects, a customized questionnaire was used (scores: 1 = applies fully; 5 = does not apply at all).

Compliance
• The questionnaire return rate was defined as returned/ delivered patient-completed questionnaires (questionnaires were completed at all 621 patients.
• Compliance on oral capcitabine intake was assessed by a customized questionnaire (compliance = 13–14 days / cycle; b.i.d)

Response (reported by investigator assessment):
• Response rate was defined as the sum of complete responses (CR) plus partial responses (PR).
• Clinical benefit rate was defined as the sum of CR plus PR plus stable disease (SD) cases.

RESULTS

Patient demographics and treatment characteristics:
• 739 of 750 planned patients had been registered until 10/2011, and 622 of these were documented to have received at least one cycle of capcitabine.
• The average age of the patients was 62.2 (± 11.1) years
• 45% (n=327) of the patients received capcitabine monotherapy and 55% (n=343) combination therapy (Fig. 1).
• Patients receiving combination therapy for treatment of MBC were younger (Fig. 2).
• For combination therapy capcitabine was most commonly combined with bevacizumab, lapatinib, vinorelbine or trastuzumab (Tab. 1).

Quality of life:
• QLC20 data for 556 patients (89.5%) are available for up to 12 cycles of capcitabine treatment (Fig. 3 a).
• Mean values (all patients) for global health status/QoL (Fig. 3a) increased slightly throughout capcitabine treatment, whereas mean values for cognitive functioning tended to decline steadily (Fig. 3b). Mean scores (all patients) for role functioning (Fig. 3c), emotional functioning (Fig. 3d) and social functioning (Fig. 3e) remained stable.
• Compliance:
• Questionnaire return rate ranged between 88% (baseline) and 61% (cycle 12).
• Compliance rate of oral capcitabine intake was between 84.5% (cycle 1) and 73.2% (cycle 12).
• Patients reported interruption of capcitabine therapy most frequently as a result of hand-foot syndrome (49 patients), nausea/emesis (12 patients) and diarrhea (10 patients).

Patient satisfaction:
• Patient satisfaction regarding information of their treating physician on cancer treatment and side effects was high (mean >4 out of 5).
• Overall satisfaction on cancer treatment was evaluated by 10.3% of the patients as equal or better than expected (n=144 out of 226).

Response rates:
• CR or PR was achieved by 61 patients (31.3%) receiving capcitabine monotherapy and 123 patients (46.7%) receiving combination therapy across all treatment cycles (Tab. 2).
• Clinical benefit rates were 72.4% for monotherapy and 76.0% for combination therapy, respectively (Tab. 2).
• No mature data were available on progression-free survival at the time of analysis.

CONCLUSIONS

• In this non-interventional surveillance study in Germany, capcitabine was most commonly used in the first-line setting and the most common combination partner was bevacizumab.
• Patients receiving capcitabine combination therapy for treatment of MBC were younger.
• Available data from up to 12 cycles of treatment in 556 patients indicate that QoL is stable during capcitabine therapy.
• Slightly higher (but non-significant) QLC20 scores were achieved with capcitabine combination therapy.
• 31% of patients receiving capcitabine monotherapy and 47% receiving capcitabine combination therapy achieved a CR or PR across all therapy lines.
• Compliance rates ranged between 84.5% (cycle 1) and 73.2% (cycle 12).
• Overall satisfaction on capcitabine treatment was evaluated by more than half of the patients as equal or better than expected.

REFERENCES

Table 2. Best response with capcitabine monotherapy or combination therapy

Table 3. Best response by metastatic treatment line

Table 1. Percentages of patients receiving capcitabine monotherapy or combination chemotherapy

Figure 1. Mean age of patients receiving capcitabine monotherapy or combination chemotherapy

Figure 2. Percentage of patients receiving capcitabine monotherapy or combination chemotherapy

Figure 3a-c. Change in QLC20 scores during capcitabine therapy. Higher QLC20 scores represent better functioning.