ObJectIve

The primary objective of this study was to evaluate wound-healing complications (WHC) following surgery among patients with metastatic colorectal cancer (mCRC) who were receiving Bevacizumab (BV) + chemotherapy as their first-line treatment. This observational study, called BRiTE (Bevacizumab: RETrospective Observational Tumor Eval- uation), was conducted at 107 centers globally and included patients who had undergone surgery (on- or off-study) while on or after starting treatment with BV + chemotherapy. The study was divided into two phases: the BRiTE observational cohort study (Phase I) and the BRiTE observational case control study (Phase II).

Methods

Study Design

This was a retrospective, observational study with baseline factors collected at the time of enrollment. The study was conducted at 107 centers globally and included patients who had undergone surgery (on- or off-study) while on or after starting treatment with BV + chemotherapy. The study was divided into two phases: the BRiTE observational cohort study (Phase I) and the BRiTE observational case control study (Phase II).

Patients

Patients were eligible for the study if they had metastatic colorectal cancer (mCRC) or locally advanced and unresectable colorectal cancer (CRC) and had received BV in combination with other cytotoxic chemotherapy agents for their metastatic or locally advanced disease. Patients were required to have adequate hematological, hepatic, and renal function at baseline. The primary endpoint of the study was the incidence of serious wound-healing complications (sWHC) following surgery in patients who received BV + chemotherapy as first-line treatment.

Results

A total of 622 mCRC patients had surgery after starting treatment with first-line BV + chemotherapy. Of these, 23 patients (3.7%) experienced sWHC, including infection at the operative site (11 patients), wound dehiscence (5 patients), bleeding at the operative site (3 patients), and delayed wound healing (2 patients). The rates of sWHC among BRiTE participants, by specific baseline factor, are shown in Table 1.

Conclusion

Serious wound-healing complications following surgery are uncommon in patients with metastatic colorectal cancer receiving BV + chemotherapy. The incidence of sWHC among BRiTE participants was 3.7%. Additional factors possibly associated with WHC included infection at the operative site (11 patients), wound dehiscence (5 patients), bleeding at the operative site (3 patients), and delayed wound healing (2 patients). The low number of events precluded a multivariate analysis to further evaluate risk factors.