Results of a randomized phase 3 study evaluating the potential benefit of a second-look surgery plus HIPEC in patients at high risk of developing colorectal peritoneal metastases (PROPHYLOCHIP- NCT01226394).

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Abstract Disclosures

Background: Complete cytoreductive surgery (CRS) followed by hyperthermic intraperitoneal chemotherapy (HIPEC) allow to prolong survival in patients with colorectal peritoneal metastases (CRPM), especially with a low tumor burden. The aim of the PROPHYLOCHIP multicentric randomized phase 3 study was to evaluate the potential survival benefit of a systematic second-look surgery plus HIPEC in patients at high risk of developing CRPM.

Methods: Patients at high risk of developing CRPM defined as minimal CRPM resected with the primary, or history of ovarian metastases, or perforated primary tumor, were eligible. After 6 months of adjuvant chemotherapy, patients without sign of recurrence were randomized into 2 arms: (1) surveillance, (2) systematic second-look surgery plus HIPEC (intraperitoneal oxaliplatin). The primary end-point was the 3-year disease-free survival (DFS). Secondary end-points included overall survival (OS), peritoneal DFS and postoperative complications.

Results: Between 2012 and 2015, 150 patients were randomized. During the second-look laparotomy (n = 71), CRPM was diagnosed in 52%, with a median peritoneal cancer index of 4 [0-26]. No patient died postoperatively and grade 3-4 complications occurred in 41%. After a median follow-up of 51 [47-55] months, the 3-year DFS of 44% [33-56] in the second-look group and of 51% [40-62] in the surveillance group did not differ (p = 0.75). In the surveillance group, a peritoneal relapse occurred in 25 (33%) patients, which was accessible to CRS-HIPEC in 16, whereas in the second-look group, 24 (32%) patients had a peritoneal relapse of whom 2 were treated with a new CRS-HIPEC. The 3-year OS was not significantly different, 80% [69-88] and 79% [68-87] in the surveillance and in the second-look groups, respectively.
Conclusions: This study confirms that criteria for high risk of developing PM are strong, and strengthens the role of a peritoneal-centered surveillance in these patients. However, a pro-active strategy including a systematic second-look surgery plus HIPEC failed to improve survival, in comparison to an adequate surveillance. Clinical trial information: NCT01226394

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