

Preoperative chemosensitivity testing as predictor of treatment benefit in adjuvant stage III colon cancer: Preliminary analysis of the PePiTA study.

Background: Although being the standard-of-care for stage III colon cancer, no biomarkers can identify patients (pts) who benefit from adjuvant chemotherapy. In metastatic pts, the lack of metabolic response (mR) in FDG-PET/CT after 1 chemotherapy cycle predicts the absence of treatment benefit. The PePiTA study aims to evaluate if the absence of mR after 1 cycle of pre-operative chemotherapy is predictive of recurrence in non-metastatic colon cancer pts. Herein, we report a preliminary analysis on surgical outcomes, adverse events and mR assessment after 1 cycle of pre-operative chemotherapy after completing the study accrual objective. **Methods:** Colon cancer pts eligible for curative resection and ECOG ≤ 1 received 1 cycle of mFOLFOX followed by surgery in this prospective, multicentre, non-randomized trial. FDG-PET/CT was performed at baseline and after 1 cycle of mFOLFOX. Adjuvant mFOLFOX was administered for up to 12 cycles for stage III pts, whereas for stage II pts the decision to pursue adjuvant chemotherapy was at investigator's discretion. A decrease $\geq 15\%$ in SUVmax after 1 cycle of chemotherapy was defined as mR (EORTC criteria) at central review. **Results:** mR was assessable on the primary tumor in 204/240 pts (85%). In 11 pts (4.6%), staging was modified by the baseline FDG-PET/CT, which detected metastatic disease or other tumors. Pre-operative mFOLFOX was administered to 218 pts, of which 14 (6%) had a grade ≥ 3 adverse event. Surgery was performed in 218 pts, with a median delay of 20 days (6 to 59) after chemotherapy. Surgical complications occurred in 28 (13%) pts, however no deaths occurred. The median SUVmax decrease between baseline and 2nd FDG-PET/CT was 24%. A mR was observed in 65.2% of the pts, whereas 34.8% showed no mR, including 3% who had progressive disease. **Conclusions:** One cycle of pre-operative mFOLFOX followed by a mR assessment has shown to be a feasible and safe strategy, raising interest on the potential of neoadjuvant chemotherapy in colon cancer. The early mR assessment identified pts that may not benefit from chemotherapy and might have a worse prognosis. The substantiation of this hypothesis is expected with the study's long-term results. [Clinical trial information: NCT00994864](https://clinicaltrials.gov/ct2/show/study/NCT00994864).

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