FOLFIRI followed by radiochemotherapy and surgery in locally advanced gastric cancer:

FFCD 0308 phase II trial.

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Abstract:

Background: In locally advanced gastric cancer, perioperative chemotherapy (CT) is often recommended. The chemoradiotherapy (CTRT) interest is supported by the high risk of regional recurrence. The aim of this trial was to assess the feasibility of complete treatment (CT+CTRT+surgery) with a CT regimen efficient and well tolerated in metastatic phase.

Methods: Histologically proven gastric carcinoma, with T3 and or N+, M0 according to CTscan or endoscopic ultrasound, WHO status ≤ 1 and allowing major surgery were eligible in this phase II multicenter study. The treatment consisted of 4 courses of FOLFIRI followed by concomitant CTRT (45 Gy at 1.8 Gy per fraction in 5 weeks, 5FU 200 mg/mg^2 days 1 to 5 each week of radiotherapy), followed by surgical resection with partial or total gastrectomy according to the localization of the tumor 30 days after, with D1 or D2 lymphadenectomy. A

complete treatment was defined by full CT courses, at least 22.5 fractions of RT (90% fractions) and 75% of the 5FU dose, followed by at least surgical exploration. A feasibility rate of 70% was considered uninteresting, 88% being expected. A Fleming two stages design required more than 34 complete treatments in 42 pts to assert the treatment feasibilty (unilateral alpha 5%, power 83%). Analyses were performed in intent to treat.

Results: The 42 pts were included between September 2007 and January 2010 in 16 centers, with a mean age of 60.5 yrs (30-78), serum albumin 38.9 g/l (18-52), 59.5% with performance status 0. All courses of FOLFIRI, 90% RT and 75% of FU during CTRT, and surgery were performed in 39, 34 and 35 pts respectively. Complete treatment was performed in 31/42 pts (73.8%, 95% CI : 60.5-87.1), 28 pts had a R0 resection (80.0%), and 17 pts (40.5%) had at least one severe advserse event (grade 3-4). During FOLFIRI and CTRT, at least one severe adverse event (grade 3-4), was reported in 11 (26.2% , 95% CI: 13.9-42.0) and 8 pts (19.0% 95%CI: 8.6-34.1%) respectively. The post-operative death rate was 5.71%.

Conclusions: The feasibility of the therapeutic sequence FOLFIRI–radiotherapy with 5FU-surgery is not significantly higher than 70%. According to the study design, this association would not be recommended.