

# Abstract #81168

Haut du formulaire

Geriatric factors to predict toxicity and dose-intensity reduction in FFCD 2001-02 phase III study comparing a first-line chemotherapy of LV5FU2 or FOLFIRI in treatment of metastatic colorectal cancer (mCRC) in elderly patients.

T. Aparicio, J. L. Jouve, L. Teillet, D. Gargot, V. Le Brun Ly, J. Cretin, C. Locher, O. Bouche, G. Breysacher, J. Charneau, J. F. Seitz, M. Gasmi, F. Ricard, F. Subtil, E. Mitry, ; Hôpital Avicenne, APHP, Bobigny, France; University Hospital, Dijon, France; Hôpital Sainte Péline, APHP, Paris, France; CH Blois, Blois, France; CHU Dupuytren, Limoges, France; GINECO, Nimes, France; Department of Hepato-Gastroenterology, Meaux Hospital, Meaux, France; University Hospital Robert Debre, Reims, France; Hôpitaux Civils de Colmar, Colmar, France; CH Boulogne, Boulogne sur Mer, France; APHM La Timone, Marseille, France; Hôpital Nord APHM, Marseille, France; Fédération Francophone de Cancérologie Digestive, Dijon, France; FFCD, Dijon, France; Institut Curie, St. Cloud, France

Abstract Text:

**Background:** Elderly patients form a heterogeneous population. The evaluation of geriatric factors could help the selection of eligible patients for an intensified chemotherapy. **Methods:** Elderly pts (75+) with previously untreated mCRC were randomly assigned to receive a 5FU-based CT, either alone (FU arms: LV5FU2 or simplified LV5FU2) or in combination with irinotecan (IRI arms: LV5FU2-CPT11 or FOLFIRI) from 2003 to 2010. Sites participating to the geriatric sub-study, completed Karnofsky, Charlson index and a visual analogue scale (VAS) of quality of life (QoL) at inclusion. Cognitive function, autonomy and depression were assessed with MMSE, IADL and GDS score respectively. Clinical and biologic tumour factors were also analysed to determine predictive factors of grade 3-4 toxicity and reduction of chemotherapy dose-intensity >33% during the first 4 months after randomization. **Results:** Geriatric score were fulfilled in 123 (48%) pts randomized in FFCD 2001-02 study. Median age: 80 years [75 to 91], 66 men (54%), FU 50.4%, IRI 49.6%. Karnofski index was 60-70, 80-90 and 100 in 32, 32 and 36% of pts respectively and Charlson was <1 or >1 in 75 and 24% of them. Median QoL VAS: 7.9 and median MMSE: 28/30. GDS and IADL were impaired in 45% and 37% of the pts. Seventy-one (58%) pts had a grade 3-4 toxicity and 81 (66%) pts had a dose-intensity reduction >33% during the first 4 months after randomization. In multivariate analysis significant predictive factors of a toxicity grade 3-4 were: no previous adjuvant chemotherapy OR=8.33, IRI arms OR= 3.67, MMSE  $\leq$ 27/30 OR=5.00 and impaired IADL OR=4.35. Significant predictive factors of a dose-intensity reduction >33% were: phosphatase alkaline >2N OR=8.34, IRI arms OR=6.93 and a linear decrease of MMSE OR=24.3 (each 10%). **Conclusions:** For the first time in a randomized prospective phase III study in mCCR, geriatric factors (MMSE and IADL) are predictive of severe toxicities or dose-intensity reduction. These results suggest that cognitive function and autonomy impairment should be considered for the chemotherapy regimen choice.

Title:

Geriatric factors to predict toxicity and dose-intensity reduction in FFCD 2001-02 phase III study comparing a first-line chemotherapy of LV5FU2 or FOLFIRI in treatment of metastatic colorectal cancer (mCRC) in elderly patients.

Submitter's E-mail Address:

thomas.aparicio@avc.aphp.fr

Is this a late-breaking abstract?

No

Is this abstract a clinical trial?

Yes

Is this clinical trial registered?

Yes

Registry Name:

Clinicaltrials.gov

Registration Number:

NCT00303771

Research Funding Source:

Pharmaceutical/Biotech Company

Research Funding Source Name:

Pfizer

Did the trial accrue its first patient before or after April 29, 2004?

Before

Would like to be considered for a Merit Award:

No

Trial Type:

Phase III

Research Category:

Clinical

Continued Trial Accrual:

No

Received Grant funding:

No

All participants were over the age of 65:

Yes

**Sponsor:** Laurent Bedenne, MD

First Author

Presenting Author

Thomas Aparicio, MD, PhD

Hôpital Avicenne, APHP

Bobigny,

France

**Phone Number:** 33 148 955 431

**Email:** thomas.aparicio@avc.aphp.fr

[Click to view Conflict of Interest Disclosure](#)

Second Author

Jean-Louis Jouve, MD

University Hospital

Dijon,

France

**Email:** jean-louis.jouve@chu-dijon.fr

[Click to view Conflict of Interest Disclosure](#)

Third Author

Laurent Teillet, MD, PhD

Hôpital Sainte Péline, APHP

Paris, 75116

France

**Email:** laurent.teillet@spr.aphp.fr

[Click to view Conflict of Interest Disclosure](#)

Fourth Author

Dany Gargot, MD

CH Blois

Blois,

France

**Email:** dgargot@ch-blois.fr

[Click to view Conflict of Interest Disclosure](#)

Fifth Author

Valerie Le Brun Ly, MD

CHU Dupuytren

Limoges,

France

**Email:** v.lebrun-ly@chu-limoges.fr

[Click to view Conflict of Interest Disclosure](#)

Sixth Author

Jacques Cretin, MD

GINECO

Nimes,

France

**Phone Number:** 04 66 62 58 03 (Secrétariat)

**Email:** cretinjacques@yahoo.fr

[Click to view Conflict of Interest Disclosure](#)

Seventh Author

Christophe Locher, MD

Department of Hepato-Gastroenterology, Meaux Hospital

Meaux,

France

**Phone Number:** 33 164 353 854

**Email:** c-locher@ch-meaux.fr

[Click to view Conflict of Interest Disclosure](#)

Eighth Author

Olivier Bouche, MD, PhD

University Hospital Robert Debre

Avenue du Général Koenig

Reims,

France

**Phone Number:** +33-326787172

**Fax Number:** +33-326788836

**Email:** obouche@chu-reims.fr

[Click to view Conflict of Interest Disclosure](#)

Ninth Author

Gilles Breysacher, MD

Hôpitaux Civils de Colmar

Colmar, 68000

France

**Phone Number:** 333-891-240-97

**Email:** gilles.breysacher@ch-colmar.rss.fr

[Click to view Conflict of Interest Disclosure](#)

Tenth Author

Jacky Charneau, MD

CH Boulogne

Boulogne sur Mer,

France

**Email:** j.charneau@ch-boulogne.fr

[Click to view Conflict of Interest Disclosure](#)

Eleventh Author

Jean-François Seitz, MD, PhD

APHM La Timone

Gastroenterology, Boulevard Jean-Moulin

Marseille, 13005

France

**Phone Number:** 0491386023

**Fax Number:** 04

**Email:** jean-francois.seitz@mail.ap-hm.fr

[Click to view Conflict of Interest Disclosure](#)

Twelfth Author

Mohamed Gasmi, MD

Hôpital Nord APHM

CHEMIN DES BOURRELY

GASTRO ENTEROLOGIE

Marseille, 13915 CEDE

France

**Email:** mohamed.gasmi@ap-hm.fr

[Click to view Conflict of Interest Disclosure](#)

Thirteenth Author

Floriane Ricard

Fédération Francophone de Cancérologie Digestive

Dijon,

France

**Email:** floriane.ricard@u-bourgogne.fr

[Click to view Conflict of Interest Disclosure](#)

Fourteenth Author

Fabien Subtil

FFCD

Dijon,

France

**Email:** fabien.subtil@u-bourgogne.fr

[Click to view Conflict of Interest Disclosure](#)

Fifteenth Author

Emmanuel Mitry, MD, PhD

Institut Curie

St. Cloud,

France

**Phone Number:** 33 1 47111850

**Email:** emmanuel.mitry@curie.net

**Alternate Email:** e.mitry@me.com

[Click to view Conflict of Interest Disclosure](#)

Group

Federation Francophone de Cancerologie Digestive