A phase II study of radiation and Docetaxel and Cisplatin in the treatment of locally advanced pancreatic carcinoma. FNCLCC-ACCORD 09/0201 trial.

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ABSTRACT #4625

Background: Locally advanced pancreatic carcinoma remains a challenging tumor with no clear standard of care in terms of radio-chemotherapy. The purpose of this phase II trial was to determine the efficacy and the toxicity of radiotherapy and docetaxel and cisplatin in histologically proven adenocarcinoma of the pancreas.

Methods: Patients (pts) received external beam radiotherapy (54 Gy in 1.8 Gy fractions, six weeks) and weekly chemotherapy regimen of association docetaxel and cisplatine (20 mg/m2/weeks each) for six weeks.

Results: 51 pts (20 women and 31 men, with median age of 62 years) with disease considered to be unresectable but confined to pancreas area and celiac nodes were included between 06/10/2003 and 15/02/2008. Location of the tumor: head (33 pts), body (13 pts), and tail (5 pts). The median dose of radiotherapy received by the patients was 54 Gy. The median dose of docetaxel and cisplatin administered was 19.8 mg/m2/w (relative dose intensity 97%). Radiotherapy has to be interrupted in 7 pts. 30 pts experienced at least one episode of grade 3 or 4 toxicity (asthenia 12 pts, anorexia 11 pts, vomiting 10 pts, nausea 9 pts, abdominal pain 5 pts). No toxic death was observed. 6 pts underwent secondary pancreatic resection (4 compete resection and 1 pt with histological complete remission). The objective response rate (CR 5 pts, PR 3 pts), was 16% with a median duration of 7.6 months. At 6 months, 30 pts had progressed. Median progression free survival was 5.8 months. With a 21 months median follow up, median overall survival was 9.6 months and 18 months survival rate of 31%.

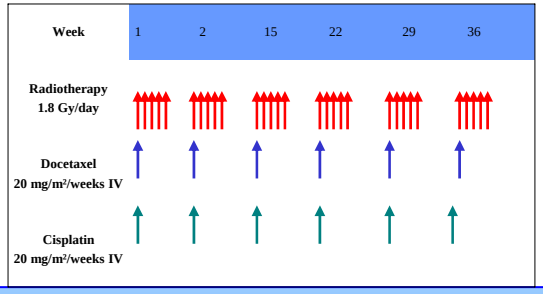
Conclusion: The association docetaxel+cisplatin+radiotherapy has limited effect in patients with locally advanced pancreatic carcinoma but major objective responses have been observed allowing secondary resections. Grant by Sanofi-Aventis, Amgen and Ligue Nationale Contre Le Cancer.

INTRODUCTION

Locally advanced pancreatic carcinoma remains a challenging tumor with no clear standard of care in terms of radio-chemotherapy. The purpose of this phase II trial was to determine the efficacy and the toxicity of radiotherapy and docetaxel + cisplatin in histologically proven adenocarcinoma of the pancreas.

MATERIALS AND METHODS

- **Locally advanced/inoperable pancreatic adenocarcinoma**
- **ECOG performance status < 1**
- **Adequate organ function**
- **No prior chemotherapy or radiotherapy**
- **No distant metastases**
- **54 Gy with standard fractionation**

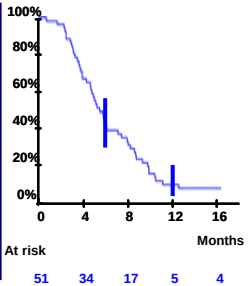


RESULTS

- **51 pts (20 women and 31 men, with median age of 62 years), were included between 06/10/2003 and 15/02/2008.**
- **Location of the tumor: head (33 pts), body ± head (13 pts), tail ± body (5 pts).**
- **The median dose of radiotherapy received by the patients was 54 Gy [range 22 - 56].**
- **The median weekly dose of docetaxel and cisplatin administered was 19.8 mg/m²/w.**
- **30 patients experienced at least one episode of grade 3/4 toxicity.**
- **No toxic death was observed.**

	Grade 1/2	Grade 3/4
Anorexia	45%	22%
Diarrhea	55%	6%
Nausea	65%	18%
Vomiting	45%	20%
Abdominal pain	63%	10%
Asthenia	49%	24%
Neutropenia	22%	8%

- **At 6 months, 34 patients had progressed.**
- **6 patients underwent secondary pancreatic resection :**
  - ✓ **4 complete resection**
  - ✓ **and 1 with histological complete response.**
- **With a 22.7 months median follow up :**
  - ✓ **median progression free survival was 5.5 months**
  - ✓ **and median overall survival was 9.6 months.**
- **Survival rate at 6, 12 and 18 months was 80.4%, 41% and 30.5% respectively.**



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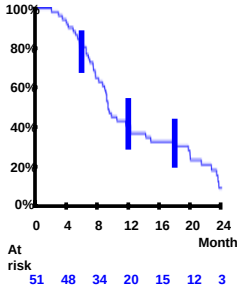

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CONCLUSION

The association docetaxel + cisplatin + radiotherapy has limited effect in patients with locally advanced pancreatic carcinoma but major objective responses have been observed allowing secondary resections.

Acknowledgements

- Patients ans Families
- Co-investigators : Joël EZENFIS, David MALKA, Anne-Laure VILLING, Valérie BOIGE Institut Gustave Roussy (VILLEJUIF) ; Marc GIOVANNINI Anne-Laure MADROSZYK-FLANDIN, Valérie MAGNIN, Carole TARPIN Institut Paoli Calmettes (MARSEILLE) ; Stéphanie BORDENAVE-CAFFRE, Gérard DABOUIS, Jean-Yves DOUILLARD, Emmanuel RIO, Hélène SENELLART, Centre René Gauducheau (NANTES ST HERBLAIN) ; David AZRIA, Carmen LACER-MOSCARDO, Claire LEMANSKI, Pierre SENESSE, Centre Val d'Aurelle (MONTPELLIER) ; Thierry CONROY, Centre Alexis Vautrin (VANDOEUVRE LES NANCY) ; Patrice CELLIER, Virginie BERGER, Véronique GUERIN-MEYER, Dominique LUET, Philippe MAILLART, Pierre-Marie PABOT DU CHATELARD, Centre Paul Papin (ANGERS) ; Nathalie DELIGNY, Sophie DOMINGUEZ, Xavier MIRABEL, Centre Oscar Lambret, (LILLE) ; Barbara LAMORTE-DIEUMEGARDE, Fawzia MEFTI-LACHERAF, Centre René Huguenin,(SAINT-CLOUD) ; Françoise MORNEX Hôpital Lyon Sud (PIERRE BENITE)- France
- Sponsor : J. Genève, M. Torres-Macque, AC. Le Gall, (FNCLCC, BECT, Paris)
- Data manager : M. Abbas
- Grants from sanofi-aventis et Amgen