

## Poster Discussion Presentations (Sun, 25 Sep, 11:15–12:15)

### Gastrointestinal Malignancies – Colorectal Cancer

6008

POSTER DISCUSSION

#### The Cell Saver is Safe to Use in Rectal Cancer Surgery

R. Dudink<sup>1</sup>, I. Martijnse<sup>1</sup>, R. Stokmans<sup>1</sup>, D. Wasowicz-Kemps<sup>1</sup>, G. Nieuwenhuijzen<sup>1</sup>, F. Holman<sup>1</sup>, M. Kusters<sup>1</sup>, R. Hendrickx<sup>2</sup>, V. Lemmens<sup>3</sup>, H. Rutten<sup>1</sup>. <sup>1</sup>Catharina Hospital, Surgery, Eindhoven, The Netherlands; <sup>2</sup>Catharina Hospital, Extracorporeal Circulation, Eindhoven, The Netherlands; <sup>3</sup>Comprehensive Cancer Centre South, Eindhoven Cancer Registry, Eindhoven, The Netherlands

**Background:** Preservation techniques for the patient's own blood during cancer surgery have not been adopted widely for fear of introducing viable tumour cells, which may give rise to metastases. However, the use of fresh autologous blood is related to better post-operative outcome and less morbidity and mortality. In this study we present our results of using the cell saver in surgery for locally advanced and recurrent rectal cancer.

**Material and Methods:** From 1994 until August 2010, data on 546 patients who have been treated for locally advanced (n = 444) or recurrent (n = 102) rectal cancer was collected prospectively. For more than ten years, the cell saver was used to collect, filter, wash and return the patient's own erythrocytes. Blood was not returned when contaminated by faeces or pus or when no transfusion was deemed indicated. Four quartiles representing the volume of blood loss were created: Q1 less than or equal to 1250 ml (n = 153), Q2 1251 up to 2500 ml (n = 140), Q3 2501 up to 5000 ml (n = 138), Q4 5001 ml or more (n = 115).

**Results:** For locally advanced and recurrent rectal cancer, surgery is complex and extra-anatomically. Hence mean blood loss was 3697 millilitres, 3110 millilitres for locally advanced rectal cancer patients and 6209 millilitres for recurrent rectal cancer patients. Autologous blood was returned in 315 patients (58 percent). Cancer specific 5-year survival for all patients and per quartile blood loss volume was higher when the cell saver was used: 74, 78, 87, 71 and 63 percent compared to 57 (p = 0.001), 69 (p = 0.363), 62 (p = 0.054), 50 (p = 0.012) and 38 (p = 0.027) percent for those without cellsaving. Metastases free 5-year survival rates were 70, 59, 81, 70, 66 percent and 61 (p = 0.036), 72 (p = 0.743), 66 (p = 0.337), 57 (p = 0.085), 35 (p = 0.005) percent, respectively. Local recurrence rates were 12, 9, 5, 13, 22 percent and 22 (p = 0.007), 13 (p = 0.227), 17 (p = 0.047), 30 (p = 0.014), 42 (p = 0.151) percent, respectively.

**Conclusions:** Five-year cancer specific survival, metastases free survival and local recurrence rates for the whole group of patients were all statistically significant in favour of the use of the cell saver. Especially in the higher blood loss quartiles. More specifically, patients did not develop more metastases when the cell saver was used. Therefore we conclude, that introduction of the cell saver did not compromise oncological outcome and thus is safe to use in rectal cancer surgery.

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POSTER DISCUSSION

#### Progression Free and Overall Survival After Neoadjuvant Treatment of Colorectal Liver Metastases With Cetuximab Plus FOLFOX or FOLFIRI – Results of the CELIM Study

G. Folprecht<sup>1</sup>, T. Gruenberger<sup>2</sup>, W. Bechstein<sup>3</sup>, T. Lordick<sup>4</sup>, H. Lang<sup>5</sup>, J. Weitz<sup>6</sup>, T. Suedhoff<sup>7</sup>, J. Hartmann<sup>8</sup>, T. Liersch<sup>9</sup>, C. Koehne<sup>10</sup>.

<sup>1</sup>University Hospital Carl Gustav Carus, University Cancer Center/Medical Department I, Dresden, Germany; <sup>2</sup>University Hospital Vienna, Surgery, Vienna, Austria; <sup>3</sup>University Hospital Frankfurt/Main, Surgery, Frankfurt/Main, Germany; <sup>4</sup>Klinikum Braunschweig, Medical Department III, Braunschweig, Germany; <sup>5</sup>Johannes-Gutenberg-University, Surgery, Mainz, Germany; <sup>6</sup>University Hospital Heidelberg, Surgery, Heidelberg, Germany; <sup>7</sup>Klinikum Passau, Medical Department II, Passau, Germany; <sup>8</sup>University Hospital Schleswig-Holstein, Medical Department II, Kiel, Germany; <sup>9</sup>University Hospital Goettingen, Surgery, Goettingen, Germany; <sup>10</sup>Klinikum Oldenburg, Oncology and Hematology, Oldenburg, Germany

**Background:** Cetuximab plus FOLFIRI or plus FOLFOX induces high response rates in patients with k-ras wild-type, colorectal liver metastases and increases the rate of metastasectomies (Van Cutsem ASCO-GI 2011).

**Methods:** Patients with initially non-resectable colorectal liver metastases were randomized to treatment with cetuximab/FOLFOX or cetuximab/FOLFIRI and re-evaluated for resectability after eight and then every four cycles. Resectable patients were offered liver resection. KRAS status was retrospectively determined.

The response and resection rates were reported elsewhere (Folprecht et al, Lancet Oncol 2010).

**Results:** Fifty-six patients were randomized to cetuximab/FOLFOX, fifty-five to cetuximab/FOLFIRI. In all patients, the median progression free survival (PFS) was 10.8 [95% CI 9.3–12.2], the median overall survival 33.7 [26.0–40.2] months.

According to treatment arms, the median progression free survival was 11.2 [7.2–15.3] with cetuximab/FOLFOX and 10.5 [8.9–12.2] months with cetuximab/FOLFIRI. In KRAS wild-type patients, the PFS was 11.9 [8.3–15.6], in KRAS mutant patients 9.9 months [4.5–15.22].

The overall survival was 35.7 [30.0–41.5] and 29.0 [18.7–39.3] for cetuximab/FOLFOX and cetuximab/FOLFIRI, respectively, and 36.1 [25.1–47.1] and 27.4 [15.7–39.1] months for KRAS wild-type and mutant patients (not significant).

Resected patients had a significantly longer progression free survival (15.1 [12.8–17.4] vs 7.07 [6.0–8.1] months, p < 0.0001) and a significantly higher overall survival compared to non-resected patients (table 1, p < 0.0001).

**Conclusions:** Liver resection can successfully be performed after neoadjuvant treatment with cetuximab plus chemotherapy in patients with initially non-resectable liver metastases and is associated with favorable survival rates.

Table 1: Progression free and overall survival rates according to Kaplan–Meier est.

	KRAS wild-type	KRAS mutant	resected patients	not resected patients
PFS, 1 year	49.3 [6.1]	25.9 [8.4]	66.0 [6.9]	21.1 [5.4]
PFS, 2 years	17.9 [4.7]	7.4 [5.0]	23.4 [6.2]	3.5 [2.4]
PFS, 3 years	6.8 [3.2]	*	10.6 [4.5]	*
OS, 1 year	88.4 [3.9]	96.4 [3.5]	91.3 [4.2]	87.3 [4.5]
OS, 2 years	67.9 [5.6]	53.6 [9.4]	82.6 [5.6]	42.5 [6.7]
OS, 3 years	50.4 [6.2]	39.9 [9.3]	67.0 [6.7]	23.7 [5.9]

all values in % [standard error]. \*Not evaluated due to small sample size.

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POSTER DISCUSSION

#### Radiofrequency Ablation Combined With Systemic Treatment Versus Systemic Treatment Alone in Patients With Non-Resectable Colorectal Liver Metastases: a Randomized EORTC Intergroup Phase II Study (EORTC 40004)

T. Ruers<sup>1</sup>, C. Punt<sup>2</sup>, F. van Coevorden<sup>3</sup>, J. Ledermann<sup>4</sup>, G. Poston<sup>5</sup>, W. Bechstein<sup>6</sup>, M. Lentz<sup>7</sup>, M. Mauer<sup>8</sup>, M. Lutz<sup>9</sup>, B. Nordlinger<sup>10</sup>.

<sup>1</sup>Antoni van Leeuwenhoek Ziekenhuis, Department of Surgical Oncology, Amsterdam, The Netherlands; <sup>2</sup>Radboud University Nijmegen Medical Centre, Department of Medical Oncology, Nijmegen, The Netherlands;

<sup>3</sup>The Netherlands Cancer Institute, Department of Surgical Oncology, Amsterdam, The Netherlands; <sup>4</sup>University College London Hospitals, Department of Medical Oncology, London, United Kingdom; <sup>5</sup>Aintree University Hospital, Department of Surgery, Liverpool, United Kingdom;

<sup>6</sup>Klinikum Der J.W. Goethe Universitaet, Department of Surgery, Frankfurt, Germany; <sup>7</sup>EORTC Headquarters, Data Management Unit, Brussels, Belgium; <sup>8</sup>EORTC Headquarters, Statistics Department, Brussels, Belgium; <sup>9</sup>Caritas St Theresia, Department of Medical Oncology, Saarbrücken, Germany; <sup>10</sup>Centre Hospitalier Universitaire

Ambroise Pare, Department of Surgery, Paris, France

**Background:** Radiofrequency ablation (RFA) is increasingly used for treatment of non-resectable colorectal liver metastases. However, clear evidence for a clinical effect is lacking. This study investigates the possible benefits of RFA in this setting.

**Methods:** This phase II study randomly assigned 119 patients with non-resectable colorectal liver metastases and no extra-hepatic disease, between systemic treatment alone (n = 59), or systemic treatment plus RFA (n = 60). Primary objective was a 30-months overall survival (OS) rate >38% for the combined treatment group. Secondary end points were OS, progression free survival (PFS) and HRQoL.

**Findings:** The primary endpoint was met, 30-months OS rate was 61.7% (95% CI: 48.2–73.9) for the combined treatment group. However, 30-month OS for the systemic treatment group was 57.6% (95% CI: 44.1–70.4), higher than anticipated. Median OS was 45.3 for combined treatment group and 40.5 months in the systemic treatment group (p = 0.22). PFS rate at 3 years in the combined treatment group was 27.6% compared to 10.6% in the systemic treatment group (HR = 0.63, 95% CI: 0.42–0.95, p = 0.025). Median PFS was 16.8 months (95% CI: 11.7–22.1) and 9.9 months (95% CI: 9.3–13.7), respectively. The liver, either alone or in combination with extra-hepatic disease, was the first site of progressive disease in 27 patients in the combined treatment group (45%), compared to 45 patients in the systemic treatment alone group (76.3%) (p < 0.0001).

The percentage of patients treated for first progression was comparable