

PANCREATIC AND BILIARY TRACT CANCER

COMBINED MODALITY THERAPY

5-FLUOROURACIL – RADIATION

5-Fluorouracil 200 – 250 mg/m²/day CIVI Throughout radiation*

OR

5-Fluorouracil 500 mg/m²/day IVB Days 1 – 3 and 29 – 31 of radiation

Radiation All patients were prescribed 44 Gy – 45 Gy, with 1.8 Gy to 2 Gy per fraction to the gross tumor volume, regional lymphatics, and margin. An additional 10 Gy to 15 Gy were prescribed in serial conedown fields to the gross tumor volume, depending on the extent of small bowel in the field. The total prescribed to the gross tumor volume was 54 Gy to 60 Gy.

*Beginning on day 1 of radiotherapy and continuing until completion of radiotherapy.

NOTE: GITSG protocol continued monthly dosing of 5-Fluorouracil for 2 years.

References: [Mehta VK, et al. *Am J Clin Oncol* 2001;24:155 – 9](#); [Gastrointestinal Tumor Study Group. *Cancer* 1987;59:2006 – 10](#).

5- FLUOROURACIL – RADIATION FOLLOWED BY GEMCITABINE (ADJUVANT)

5- Fluorouracil 500 mg/m²/day IV* Days 1–3 and 29–31 of radiation

Radiation All patients were prescribed 45 Gy/day, 5 days per week with lateral fields limited to 10 Gy to spare kidney and liver. An additional 5.4 Gy boost was prescribed to tumor bed for a total dose of 50.4 Gy.

Following a 4 week break after completion of chemoradiotherapy:

Gemcitabine 1000 mg/m² IV** Days 1, 8 and 15

*Administer as a rapid IV push; **Administer over 30 minutes.

Repeat gemcitabine cycle every 28 days for 4 total cycles.

Reference: [Kachnic L, et al. *Int J Cancer* 2001;96:132 – 9](#).

GEMCITABINE – RADIATION

Gemcitabine	600 mg/m ²	IV*	Q week**
Radiation	Beginning Day 1 of chemotherapy for 6 weeks: A total dose of 50.4 – 61.2 Gy was delivered using 1.8 Gy fractions.		

After completion of chemoradiation therapy:

Gemcitabine	1000 mg/m ²	IV*	Days 1, 8 and 15
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Repeat cycle every 28 days for 6 cycles.

*Administer over 30 minutes; **Administer once weekly for 6 weeks given 60 minutes prior to radiation therapy.

Reference: [Li CP, et al. *Int J Radiat Oncol Biol Phys* 2003;57:98 – 104.](#)

PANCREATIC/BILIARY TRACT CANCER CHEMOTHERAPY

5-FLUOROURACIL – LEUCOVORIN

Leucovorin 20 mg/m²/day IV Days 1 – 5

Followed by

5-Fluorouracil 425 mg/m²/day IVB Days 1 – 5

Repeat cycle every 28 days for 6 cycles as adjuvant treatment.

Reference: [Neoptolemos JP, et al. *N Engl J Med* 2004;350:1200 –10.](#)

GEMCITABINE

CYCLE 1

Gemcitabine 1000 mg/m² IV* Days 1, 8, 15, 22, 29, 36 and 43**

*Administer over 30 minutes; **Administer weekly for 7 weeks, followed by a 1 week rest period.

CYCLE 2 ONWARDS

Gemcitabine 1000 mg/m² IV Days 1, 8 and 15

*Administer over 30 minutes.

Repeat cycle every 28 days.

Reference: [Burris HA, et al. *J Clin Oncol* 1997;15:2403 – 13.](#)

GEMCITABINE (ADJUVANT)

Gemcitabine 1000 mg/m² IV* Days 1, 8 and 15

*Administer over 30 minutes.

Chemotherapy began within 6 weeks following complete surgical resection.

Repeat cycle every 28 days for 6 cycles.

Reference: [Oettle H, et al. *JAMA* 2007;297:267 – 77.](#)

GEMCITABINE FDR (FIXED DOSE RATE)

Gemcitabine 11000–21500 mg/m² IV* Days 1, 8 and 15

*Administer over 150 minutes at a rate of 10 mg/m²/minute.

Repeat cycle every 28 days.

References: ¹[Gelibter A, et al. *Cancer* 2005; 104:1237 – 45;](#) ²[Tempero M, et al. *J Clin Oncol* 2003;21:3402 – 8.](#)

GEMCITABINE – CAPECITABINE

Gemcitabine	1000 mg/m ²	IV*	Days 1 and 8
Capecitabine	650 mg/m ² BID	PO**	Days 1 – 14

*Administer over 30 minutes; **Administer every 12 hours within 30 minutes after the end of a meal.

NOTE: Capecitabine dose should be rounded to the nearest 150 mg or 500 mg tablet size.

Repeat cycle every 21 days until disease progression or unacceptable toxicity, to a maximum of 8 cycles.

Reference: [Herrmann RH, et al. *J Clin Oncol* 2007;25:2212 – 7.](#)

GEMCITABINE – ERLOTINIB

CYCLE 1

Gemcitabine	1000 mg/m ²	IV*	Days 1, 8, 15, 22, 29, 36 and 43
Erlotinib	150 mg/day	PO	Daily

Following completion of gemcitabine, allow a 7 day rest period, then administer:

CYCLE 2 – ONWARDS

Gemcitabine	1000 mg/m ²	IV*	Days 1, 8 and 15
Erlotinib	150 mg/day	PO	Daily onwards

*Administer over 30 minutes.

Repeat cycle every 28 days

NOTE: EGFR status determination not required.

Reference: [Moore MJ, et al. *J Clin Oncol* 2007;25:1960 – 6.](#)

GEMCIS (GEMCITABINE–CISPLATIN)

CYCLE 1

Cisplatin	25 mg/m ²	IV*	Days 1, 8, 15, 29, 36 and 43
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Followed by

Gemcitabine	1000 mg/m ²	IV**	Days 1, 8, 15, 22, 29, 36 and 43
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Followed by 2 weeks rest, THEN

CYCLE 2 AND CYCLE 3

Cisplatin	25 mg/m ²	IV*	Days 1, 8 and 15
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Followed by

Gemcitabine	1000 mg/m ²	IV**	Days 1, 8 and 15
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*Administer over 1 hour with routine pre- and post-hydration; **Administer over 30 minutes.

Repeat cycle every 28 days for 2 cycles.

Reference: [Colucci G, et al. *Cancer* 2002;94:902 – 10.](#)

GEMOX (GEMCITABINE–OXALIPLATIN)

Gemcitabine	1000 mg/m ²	IV*	Days 1 and 8
Oxaliplatin	100 mg/m ²	IV**	Day 1

*Administer over 30 minutes; **Administer over 2 hours.

Repeat cycle every 21 days.

Reference: [Alberts SR, et al. *Ann Oncol* 2003;14:580 – 5.](#)

GEMOX FDR (GEMCITABINE FDR – OXALIPLATIN)

Gemcitabine	1000 mg/m ²	IV*	Day 1
Oxaliplatin	100 mg/m ²	IV**	Day 2

*Administer over 100 minutes at 10 mg/m²/minute; **Administer over 2 hours.

NOTE: FDR = Fixed Dose Rate.

Repeat cycle every 14 days.

References: [Louvvet C, et al. *J Clin Oncol* 2005;23:3509 – 16;](#) [Louvvet C, et al. *J Clin Oncol* 2002;20:1512 – 8.](#)

GTX (GEMCITABINE – DOCETAXEL – CAPECITABINE)

Gemcitabine	750 mg/m ²	IV*	Days 4 and 11
Docetaxel [‡]	30 mg/m ²	IV	Days 4 and 11
Capecitabine	500 mg/m ² BID	PO	Days 1 – 14

[‡]Routine premedication required; *Administer over 75 minutes (FDR).

NOTE: Capecitabine dose should be rounded to the nearest 150 mg or 500 mg tablet size.

Repeat cycle every 21 days.

Reference: [Fine RL, et al. *Proc Am Soc Clin Oncol* 2004;22\(14S\):380s \[Abstract 4271\].](#)

CHOLANGIOCARCINOMA

SEE PANCREATIC SECTION

GEMCIS (GEMCITABINE – CISPLATIN)

Gemcitabine	1250 mg/m ²	IV*	Days 1 and 8
Cisplatin	75 mg/m ²	IV**	Day 1

*Administer over 30 minutes; **Administer over 2 hours with routine pre- and post-hydration.

Repeat cycle every 21 days until disease progression or unacceptable toxicity.

Reference: [Thongprasert S, et al. *Ann Oncol* 2005;16:279 – 81.](#)

GEMOX FDR (GEMCITABINE FDR – OXALIPLATIN)

Gemcitabine	1000 mg/m ²	IV*	Day 1
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Followed by

Oxaliplatin	100 mg/m ²	IV**	Day 2
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*Administer over 100 minutes at 10 mg/m²/minute; **Administer over 2 hours.

NOTE: FDR = Fixed Dose Rate.

Repeat cycle every 14 days.

Reference: [Andre T, et al. *Ann Oncol* 2004;15:1339 – 43.](#)

XELGEM (CAPECITABINE – GEMCITABINE)

Capecitabine	650 mg/m ² BID	PO	Days 1 – 14
Gemcitabine	1000 mg/m ²	IV*	Days 1 and 8

*Administer over 30 minutes.

NOTE: Capecitabine dose should be rounded to the nearest 150 mg or 500 mg tablet size.

Repeat cycle every 21 days.

Reference: [Knox JJ, et al. *J Clin Oncol* 2005;23:2332 – 8.](#)

LIVER CANCER

CLINICAL TRIAL

DOXORUBICIN

Doxorubicin	60 mg/m ²	IV	Day 1
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Repeat cycle every 21 days for 6 cycles.

Reference: [Yeo W, et al. *J Natl Cancer Inst* 2005;97:1532 – 8.](#)

PIAF (CISPLATIN – INTERFERON – DOXORUBICIN – 5-FLUOROURACIL)

Cisplatin	20 mg/m ² /day	IV*	Days 1 – 4
Interferon α 2b	5 x 10 ⁶ units/m ² /day	SQ	Days 1 – 4
Doxorubicin	40 mg/m ²	IV	Day 1
5-Fluorouracil	400 mg/m ² /day	IV**	Days 1 – 4

*Administer over 1 hour; Routine pre- and post-hydration required; **Administer as bolus.

Repeat cycle every 21 days for up to 6 cycles.

References: [Leung TWT, et al. *Clin Can Res* 1999;5:1676 – 81](#); [Yeo W, et al. *J Natl Cancer Inst* 2005;97:1532 – 8.](#)

SORAFENIB

Sorafenib	400 mg BID	PO	Continuously
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NOTE: Patients had Child-Pugh status A liver function.

Reference: [Llovet J, et al. *J Clin Oncol* 2007;25\(18S\). Abstract LBA1.](#)