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.


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.

GEMCITABINE – RADIATION

Gemcitabine 600 mg/m² 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/m² IV Days 1, 8 and 15

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.

**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.


**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.


**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.


**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.

**GEMCITABINE – CAPECITABINE**

Gemcitabine 1000 mg/m² IV* Days 1 and 8  
Capecitabine 650 mg/m² 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.


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**GEMCITABINE – ERLOTINIB**

**CYCLE 1**

Gemcitabine 1000 mg/m² IV* Days 1, 8, 15, 22, 29, 36 and 43  
Erlotinib 150 mg/day PO Daily

*Administer over 30 minutes.

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

**CYCLE 2 – ONWARDS**

Gemcitabine 1000 mg/m² 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.

GEMCIS (GEMCITABINE–CISPLATIN)

CYCLE 1
Cisplatin 25 mg/m² IV* Days 1, 8, 15, 29, 36 and 43

Followed by

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

Followed by 2 weeks rest, THEN

CYCLE 2 AND CYCLE 3
Cisplatin 25 mg/m² IV* Days 1, 8 and 15

Followed by

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

*Administer over 1 hour with routine pre- and post-hydration; **Administer over 30 minutes.

Repeat cycle every 28 days for 2 cycles.


GEMOX (GEMCITABINE–OXALIPLATIN)

Gemcitabine 1000 mg/m² IV* Days 1 and 8

Oxaliplatin 100 mg/m² IV** Day 1

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

Repeat cycle every 21 days.


GEMOX FDR (GEMCITABINE FDR – OXALIPLATIN)

Gemcitabine 1000 mg/m² IV* Day 1

Oxaliplatin 100 mg/m² 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.

**GTX (GEMCITABINE – DOCETAXEL – CAPECITABINE)**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Route</th>
<th>Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gemcitabine</td>
<td>750 mg/m²</td>
<td>IV</td>
<td>Days 4 and 11</td>
</tr>
<tr>
<td>Docetaxel†</td>
<td>30 mg/m²</td>
<td>IV</td>
<td>Days 4 and 11</td>
</tr>
<tr>
<td>Capecitabine</td>
<td>500 mg/m²</td>
<td>BID PO</td>
<td>Days 1 - 14</td>
</tr>
</tbody>
</table>

*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.

CHOLANGIOCARCINOMA

SEE PANCREATIC SECTION

GEMCIS (GEMCITABINE – CISPLATIN)
Gemcitabine 1250 mg/m² IV* Days 1 and 8
Cisplatin 75 mg/m² 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.


GEMOX FDR (GEMCITABINE FDR – OXALIPLATIN)
Gemcitabine 1000 mg/m² IV* Day 1

Followed by
Oxaliplatin 100 mg/m² 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.


XELGEM (CAPECITABINE – GEMCITABINE)
Capecitabine 650 mg/m² BID PO Days 1 – 14
Gemcitabine 1000 mg/m² 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.

LIVER CANCER

CLINICAL TRIAL

DOXORUBICIN
Doxorubicin 60 mg/m² IV Day 1

Repeat cycle every 21 days for 6 cycles.


PIAF (CISPLATIN – INFERFERON – DOXORUBICIN – 5–FLUOROURACIL)

Cisplatin 20 mg/m²/day IV’ Days 1 – 4
Interferonα 2b 5 x 10⁶ units/m²/day SQ Days 1 – 4
Doxorubicin 40 mg/m² IV Day 1
5–Fluorouracil 400 mg/m²/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.


SORAFENIB
Sorafenib 400 mg BID PO Continuously

NOTE: Patients had Child–Pugh status A liver function.