

## 구연-1

## Efficacy of Combination Chemotherapy with Capecitabine Plus Cisplatin in Patients with Advanced Biliary Tract Cancer

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**Aims:** There is no standard palliative chemotherapy regimen in biliary tract cancers (BTCs). The aim was to assess the efficacy and safety of capecitabine (X) plus cisplatin (P) in patients with advanced or metastatic BTC.

**Patients and Methods:** Patients with unresectable BTC treated with XP between Sep 2002 and Dec 2008 at National Cancer Center, Korea were reviewed retrospectively. Histologically confirmed cases of intrahepatic cholangiocarcinoma, gallbladder cancer, and extrahepatic bile duct cancer were enrolled. Capecitabine was administered orally at a dose of 1,000 mg/m<sup>2</sup> twice a day according to the standard intermittent schedule (14 days of treatment followed by a week rest period). Cisplatin was administered intravenously on days 1 and 8 at a dose of 30 mg/m<sup>2</sup> for 30 min.

**Results:** A total of 176 patients were enrolled. One hundred eighteen patients (67%) were male and the mean age of the patients was 56 years (range 27–81). Intrahepatic cholangiocarcinoma, gallbladder cancer, extrahepatic bile duct cancer were 104, 59, and 13 cases, respectively. Among 143 assessable patients, 24 patients showed partial response (PR). A complete response (CR) was radiologically confirmed in one patient with gallbladder cancer and the response rate (RR) was 17%. Sixty two patients (43%) had stable disease, and fifty six had progressive disease (39%) yielding a disease control rate of 61%. With a median follow-up of 5.7 months, the median time-to-progression (TTP) was 3.7 months (95% CI, 3.1–4.3) and the median overall survival (OS) was 7.4 months (95% CI, 6.1–8.7). There were no significant differences in TTP and OS according to site of primary tumor. The most common grade 3–4 toxicities were nausea/vomiting (12 patients). There was no treatment-related death.

**Conclusions:** Our data suggest that the XP regimen is a well-tolerated and show moderate activity against advanced or metastatic BTC.

**Key Words:** Cholangiocarcinoma, Capecitabine, Cisplatin

구연-2

## Combination Therapy of Gemcitabine and Irinotecan in Advanced Biliary Tract Cancer: Interim Analysis of Phase II Study

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**Aim:** Biliary tract cancer (BTC) is often diagnosed at advanced stage and has a poor prognosis. Chemotherapy is palliative treatment option in advanced biliary tract cancer. The aim of this phase II trial was to evaluate the efficacy and safety of the combination therapy of gemcitabine and irinotecan in patients with previously untreated advanced BTC.

**Patients and Methods:** Patients with advanced biliary tract cancer were enrolled in this study. Patients received gemcitabine 1,000 mg/m<sup>2</sup> (day 1 and 8) and irinotecan 100 mg/m<sup>2</sup> (day 1 and 8), every 3 weeks. We performed interim analysis of 29 patients who completed the treatment.

**Results:** Among 29 patients eligible for this trial, 24 patients were treated. Nineteen and five patients had gallbladder cancer and peripheral cholangiocarcinoma. A total of 132 cycles of chemotherapy were delivered, with a median of 4.5 cycles of treatment (2–12, 95% CI) per patient. The objective response rate and disease control rate were 16.7% (4/24 patients) and 70.8% (17/24) in the treated patients. Median progression free survival was 4.4 months (2.4–6.5, 95% CI) and median overall survival was 8.6 months (3.2–14.0, 95% CI). Grade 3/4 toxicities included anemia (20.7% of patients), thrombocytopenia (10.3%), neutropenia (10.3%), AST/ALT increase (13.8%), and emesis (10.3%).

**Conclusions:** Gemcitabine and irinotecan combination chemotherapy had modest efficacy and was well tolerated in patients with advanced BTC.

## 구연-3

## Preoperative Serum CA 19-9 Level as a Predictive factor of Recurrence after Curative Resection of Biliary Tract Cancer

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**Aim:** The aim of our study was to evaluate the prognostic value of the preoperative serum CA 19-9 level to predict the recurrence after curative resection of biliary tract cancer.

**Patients and Methods:** A retrospective review of the medical records of the patients who were diagnosed as biliary tract cancer (including gallbladder cancer, and intra- and extra-hepatic duct cholangiocarcinoma) and underwent curative resection at Severance Hospital from January 2006 to December 2007 was performed. Preoperative and postoperative risk factors for recurrence were evaluated using multivariate analysis, respectively.

**Results:** A total of 116 patients were included. The optimal cutoff value for preoperative serum CA 19-9 level was 60 U/mL. Preoperative serum CA 19-9 level  $\geq 60$  U/mL was observed in 55 (47.4%) patients. Forty six patients (39.7 %) experienced recurrence for a median follow up period of 21.5 months (range, 0.1-57.1 months). Recurrence occurred in 27 out of 55 patients (49.1%) with CA 19-9 levels  $\geq 60$  U/mL, but out of 61 patients with CA 19-9 levels  $< 60$  U/mL, only 19 (31.1%) had recurrence ( $p=0.015$ ). Multivariate analysis including preoperative nodal stage, age, and gender identified the preoperative CA 19-9 level as an independent predictive factor of recurrence. Patients with the preoperative CA 19-9 levels  $\geq 60$  U/mL had a higher recurrence risk comparing to patients whose CA 19-9 levels were  $< 60$  U/mL ( $p=0.001$ , Exp(B)=2.860). Analyzing prognostic postoperative factors for recurrence preoperative CA19-9 level was correlated with histologic grade ( $p=0.004$ ).

**Conclusions:** The preoperative CA 19-9 value can predict the risk of recurrence after curative resection of biliary tract cancer. The current results also suggest that the preoperative CA 19-9 value may reflect biological behavior of the cancer cells. Preoperative CA19-9 might help to determine whether neoadjuvant or adjuvant treatment might be needed.

**Key Words:** CA 19-9, biliary tract cancer, recurrence

구연-4

## 간외담관암의 근치적 수술 후 보조 방사선요법이 예후에 미치는 영향

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**목적:** 간외담관암에 대한 근치적 수술 후 보조 항암요법이 예후에 미치는 영향에 대해서는 여러 연구들마다 상이한 결과가 보고되고 있다. 저자들은 간외담관암에 대한 근치적 목적의 수술 후 보조 방사선요법이 예후에 미치는 영향을 분석하고자 하였다.

**대상 및 방법:** 2003년 8월부터 2007년 12월까지 서울대학교병원에서 간외담관암에 대해 근치적 목적의 절제술을 시행받은 183명의 환자들을 대상으로 한 후향적 연구를 시행하였다.

**결과:** 183명의 환자 중 수술 후 보조 방사선요법을 시행받은 환자는 총 115명으로 R0 절제, R1 절제를 받은 환자에서 각각 92명(63%), 23명(72%)였고, N0 병기와 N1 병기 환자에서 각각 74명(61%), 35명(74%)였다. 평균 연령은 보조 방사선요법을 시행받은 환자에서 유의하게 낮았다(63.1세 vs. 67.2세,  $p=0.002$ ). 5명의 환자를 제외하고는 보조 방사선요법 시행 시 radiosensitizer로 항암제(5-FU 또는 Capecitabine)를 함께 투여 받았고, 73명의 환자는 보조 방사선요법 후 유지 요법으로 항암제 치료를 시행 받았다. R0 및 R1 절제군, N0 및 N1 병기군 내에서 보조 방사선요법 시행 여부에 따른 생존률을 분석한 결과, 5년 총 생존률은 N1 병기에서만 보조 방사선요법을 시행 받은 환자에서 유의하게 높았고(0% vs. 27%,  $p=0.005$ ), R0 절제, R1 절제 및 N0 병기에서는 양군간에 유의한 차이가 없었다. 5년 무병 생존률은 R0 및 R1 절제, N0 및 N1 병기에서 모두 양군간에 유의한 차이가 관찰되지 않았다. R0 및 R1 절제군, N0 및 N1 병기군 내에서 5년 총 생존률 및 무병 생존률에 유의한 영향을 미치는 인자를 분석하기 위한 다변량 분석 결과 N1 병기에서만 보조 방사선요법이 유의하게 총 생존률을 향상시키는 것으로 확인되었다( $p=0.001$ , OR 3.784).

**결론:** 간외담관암 중 N1 병기에서는 수술 후 보조 방사선요법이 총 생존률을 유의하게 향상시킬 수 있는 것으로 확인되었다. 하지만 보다 세분화된 병기와 발생 부위 등에 따른 분석이 필요할 것으로 보여지고 이를 위해서는 보다 많은 수의 환자들을 대상으로 하는 연구가 필요할 것으로 생각된다.

**Key Words:** 간외담관암, 보조 방사선요법, 예후