

AB012. S3A-1. The role of adjuvant therapy in biliary tract tumors

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Abstract: Until recently the role of adjuvant chemotherapy in biliary tract cancer was unknown. However, there are now 4 completed randomized trials 3 of which have reported and although questions remain there is now evidence on which a clinician can base an informed clinical decision. Most studies have a similar design in that they all include patients with completely resected biliary tract cancer, although there is variability in which sites are included which may affect the interpretation of the results. PRODIGE12 examined adjuvant gemcitabine and oxaliplatin in cholangiocarcinoma and gallbladder cancer. The trial was negative although probably underpowered and there was a trend towards chemotherapy being of benefit. The BCAT study examined adjuvant gemcitabine only in hilar and extrahepatic cholangiocarcinoma and was convincingly negative. JCOG1202 examined adjuvant S1 in cholangiocarcinoma and gallbladder cancer. This study has completed accrual but not as yet reported. The largest study, BILCAP, examined adjuvant capecitabine in resected cholangiocarcinoma and gallbladder cancer. This study narrowly escaped significance

on the intention-to-treat (ITT) analysis. The per protocol analysis, however, (excluding 10 patients randomized to receive capecitabine but who did not receive it) was positive with a 16 months improvement in OS from 23 to 36 months ($P=0.028$). Toxicity from chemotherapy was modest and quality of life was not demonstrably affected. Exploratory analyses suggested most benefit in patients with a R0 resection, poorly differentiated tumors, male patients and those with a good performance status. The benefit seemed less in patients with hilar tumours and the subgroup of patients with node positive, R1 resections appeared to have derived no benefit. These observations generally escaped statistical significance due to small numbers. Analyses on the resected tumors in order to define molecular subtypes that correlate with benefit and possibly allow stratification in future studies is ongoing. Further trials are needed and at present ACTICCA-01, comparing the standard regimen in advanced disease (gemcitabine-cisplatin) to capecitabine, is ongoing and recruiting well. Consideration should be given to trials of intensity modulated radiation therapy (IMRT)/stereotactic body radiotherapy (SBRT) in patients who have R1 hilar resections. Trials of neoadjuvant and adjuvant treatments are also warranted and such protocols are currently in development. At the present time, however, it is reasonable to propose adjuvant capecitabine as standard of care in most patients with resected biliary tract cancers.

Keywords: Bile duct cancer; cholangiocarcinoma; adjuvant therapy; clinical trials; capecitabine

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