Introduction: Single-agent gemcitabine (GEM) has been considered for many years as the standard first-line treatment for advanced pancreatic cancer. Recently studies show a trend towards improved survival when using a gemcitabine doublet. We conducted a phase III study comparing Gem/capecitabine (Gem-X) with Gemcitabine /Erlotinib (Gem-T) in advanced and metastatic pancreatic cancer.

Methods: There were a total of 66 patients who underwent chemotherapy for locally advanced or metastatic pancreatic cancer between January 2010 to November 2013 at our institution. Patients with advanced pancreatic cancer were stratified according to nature of disease and performance status and randomly enrolled to either Gem-X (gemcitabine 1 g/m² as day 1and 8 every 3week, 30-minute infusion and capecitabine 850mg/m² twice daily for 2 weeks with one week rest), or Gem-T (gemcitabine 1 g/m² as a 100-minute infusion on day 1 and Erlotinib100mg daily).

Results: 36 and 30 patients were allocated to the Gem-X and Gem-Tarms, respectively. Gem-X was superior to Gem-T in terms of response rate GEM-X significantly improved ORR (21.2% vs 15.9%), PFS (8.9 vs. 5.2 months); p < 0.001), and OS (12.1 vs. 10.2 months; p = 0.03) compared to GEM-T. There were higher incidences of some non-hematologic adverse events with GEM-X and GEM-T, but most were grade 1 or 2. (27.7% v 18.5%, respectively; P = .04), and clinical benefit (37.2% v 26.7%, respectively; P = .03). Median overall survival (OS) for Gem-X and Gem-T was 9.0 and 7.9 months, respectively (P = .13).

Conclusion: This study was performed to compare the efficacy of capecitabine in combination with gemcitabine compared with gemcitabine with erlotinib in patients with locally advanced or metastatic pancreatic cancer. The addition of capecitabine to gemcitabine presented promising outcomes over Gem-T in pancreatic cancer. It is worthy to further investigate which agent has the clinical advantage as a combination drug with gemcitabine for pancreatic cancer and to explore predictive markers for each regimen leading to personalized anti-cancer treatment.