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Session title: Toward Zero mobility in pancreatic surgery

Best option to prevent pancreatic fistula after distal pancreatectomy

Hiroki Yamaue

Second Department of Surgery, Wakayama Medical University, School of  
Medicine, Wakayama, Japan

#### Study 1; Randomized controlled trial

We previously reported that stapler closure for transection of a thick pancreas (>12 mm) significantly increased the incidence of pancreatic fistula after distal pancreatectomy (DP) in *Am J Surg* 2013 (Kawai, Yamaue et al). Several studies reported that pancreaticojejunostomy (PJ) of pancreatic stump reduces the incidence of pancreatic fistula after DP. However, no randomized controlled trial (RCT) has confirmed the efficacy of PJ of pancreatic stump. The aim of this study was to evaluate in a multicenter RCT whether PJ of pancreatic stump decreases the incidence of pancreatic fistula after DP compared to stapler closure.

Methods: One hundred thirty-six patients scheduled for DP were enrolled in this study at 6 high-volume surgical centers in Japan. Enrolled patients

were randomized to either stapler closure or PJ. The primary endpoint was the incidence of pancreatic fistula based on the International Study Group on Pancreatic Fistula (ISGPF).

Results: Sixty-one patients randomized to stapler and 58 patients randomized to PJ were analyzed by per-protocol. The incidence of pancreatic fistula was 37.7% (23 of 61) in the stapler closure group versus 41.4% (24 of 58) in the PJ group ( $p=0.356$ ). Pancreatic fistula grade B/C occurred in 10 patients (16.4%) with stapler closure and 6 patients (10.3%) with PJ ( $p=0.334$ ). In a subgroup analysis for thickness of pancreas  $>12$  mm, the incidence of clinically relevant pancreatic fistula occurred in 22.2% of the patients in the stapler closure group and in 6.2% of the PJ group ( $p=0.080$ )(*Kawai, Yamaue et al. Ann Surg 2016*).

#### Study 2; Reinforced stapler with bioabsorbable materials

Several previous studies have evaluated the efficacy of reinforced stapler to reduce the incidence of pancreatic fistula after DP. However, the efficacy of reinforced stapler remains controversial because of the small sample sizes.

Methods: 121 patients scheduled for DP were enrolled in this study at 11 institutions in Japan. The primary endpoint was the incidence of clinically relevant pancreatic fistula.

Results: Per-protocol analysis was performed using 105 patients, as 16 patients were excluded based on criteria for discontinuation of protocol treatment. Clinically relevant pancreatic fistula occurred in 13 (12.4%) of

105 patients. Mortality rate was 0%, although reoperations were performed in two patients (1.9%). Multivariate logistic regression analysis revealed that operative time more than 240 min ( $P=0.009$ , odds ratio 6.2) and staple line hemorrhage ( $P=0.006$ , odds ratio 8.6) were independent risk factors for clinically relevant pancreatic fistula after DP when using reinforced stapler closure.

Conclusion: The first study could not evaluate the superiority of PJ of pancreatic stump during DP to reduce pancreatic fistula compared to staple closure. However, PJ for pancreatic stump might offer a potential reduction of pancreatic fistula in cases with a thick pancreas (*Kawai, Yamaue et al. Ann Surg 2016*). The bioabsorbable mesh failed to prevent PF after DP in second study, however, one should consider to perform clinical trials with high quality, then morbidity will be toward zero in pancreatic surgery.