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#### **ORIGINAL ARTICLE**

# Prospective randomized clinical trial of a change in gastric emptying and nutritional status after a pylorus-preserving pancreaticoduodenectomy: comparison between an antecolic and a vertical retrocolic duodenojejunostomy

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#### **Abstract**

**Background:** Although an antecolic duodenojejunostomy was reported to reduce post-operative delayed gastric emptying (DGE) compared with a retrocolic duodenojejunostomy after a pylorus-preserving pancreaticoduodenectomy (PPPD), the long-term effects of these procedures have rarely been studied. The aim of this prospective, randomized, clinical trial was to investigate the influence of the reconstruction route on post-operative gastric emptying and nutrition.

**Methods:** Reconstruction was performed in 116 patients with an antecolic duodenojejunostomy (A group, n = 58) or a vertical retrocolic duodenojejunostomy (VR group, n = 58). Post-operative complications, including DGE, gastric emptying variables assessed by <sup>13</sup>C-acetate breath test and nutrition, were compared between the two groups for 1 year post-operatively.

**Results:** The incidence of DGE was not significantly different between the procedures (A group: 12.1%; VR group: 20.7%, P = 0.316). At post-operative month 1, gastric emptying was prolonged in the VR versus the A group but not significantly so. At post-operative month 6, gastric emptying was accelerated significantly in the A versus the VR group. Post-operative weight recovery was significantly better in the VR versus the A group at post-operative month 12 (percentage of pre-operative weight, A group: 93.8  $\pm$  1.2%; VR group: 98.5  $\pm$  1.3%, P = 0.015).

**Conclusions:** A vertical retrocolic duodenojejunostomy was an acceptable procedure for the lower incidence of DGE and may contribute to better weight gain affected by moderate gastric emptying.

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#### Introduction

A pylorus-preserving pancreaticoduodenectomy (PPPD) is the standard operation for peri-ampullary disease. Although operative mortality of PPPD has been reduced to less than 5%,<sup>1-4</sup> post-operative morbidity remains high, at 30% to 60%.<sup>2-4</sup> Delayed gastric emptying (DGE) is one of the most specific and frustrating complications after PPPD, with an incidence ranging from 5–60%.<sup>4,5</sup> DGE is self-limiting and can be treated conservatively; however, this complication leads to a prolonged hospital stay and worsens the patient's quality of life.

Two reconstruction methods after PPPD are associated with the transverse colon: an antecolic duodenojejunostomy and a retro-

colic duodenojejunostomy. An antecolic duodenojejunostomy is reported to offer equal or superior outcomes for the prevention of DGE compared with the retrocolic route.<sup>6–11</sup> The reported incidence of DGE with the antecolic route is below 15%, whereas that with the retrocolic route is above 30%. The incidence of DGE reported by these studies for reconstruction by the retrocolic route was considered to be high compared with the authors' experience. The authors reported previously that a vertical retrocolic duodenojejunostomy, by which the stomach and duodenum are brought down the left side of the transverse mesocolon in a straight, vertical manner, reduces the incidence of DGE.<sup>12,13</sup> However, the number of the patients was small and the period after PPPD was short in these two studies.

The aim of the present study was to perform a prospective, randomized, clinical trial to compare the incidence of DGE assessed according to the definition of the International Study Groups of Pancreatic Surgery (ISGPS)<sup>14</sup> in 116 patients undergoing either an antecolic duodenojejunostomy or a vertical retrocolic duodenojejunostomy. Although some studies reported to notice an association between DGE and reconstruction route, the post-operative effects on gastric emptying function and nutritional status have rarely been compared between the two reconstruction methods. Therefore, in this study, nutritional status and gastric emptying variables assessed by the <sup>13</sup>C-acetate breath test<sup>15–17</sup> were compared before and at 1, 3, 6, 9 and 12 months during the first year after surgery between the two reconstruction methods.

#### **Methods**

The study protocol was approved by the ethics committee of Miyazaki University, Miyazaki, Japan, and was registered with the National Clinical Database (University Hospital Medical Information Network Clinical Trials Registry as UMIN000001712). From March 2005 until July 2011, 129 patients underwent a PPPD at the Department of Surgical Oncology and Regulation of Organ Function, Miyazaki University School of Medicine. The patients who underwent a pancreaticoduodenectomy with gastric resection, subtotal stomach-preserving PD (SSPPD), additional hepatic resection and a total pancreatectomy were excluded from the study. The patients underwent standard pretreatment evaluation, randomization to an antecolic or a vertical retrocolic duodenojejunostomy, and assessment of the results, DGE, gastric emptying and nutritional status for 1 year after surgery. Patients were recruited into the study before surgery, and informed consent was obtained from all participants. The study flow chart is shown in Fig. 1. Because of their pre-operative condition, four patients who did not give their informed consent and five patients with severe comorbidity were excluded. The remaining 120 patients underwent randomization; however, four patients with post-operative severe sepsis (two undergoing each reconstruction method) were excluded. A re-operation was performed in one patient (0.8%) in the antecolic group for ischaemic perforation of the duodenojejunostomy. Post-operative mortality occurred in two patients (1.7%), one patient in the antecolic group as a result of sepsis from an intravenous catheter infection, and one patient in the vertical retrocolic group owing to liver failure associated with a vascular problem. Thus, the remaining 116 patients were divided into two groups: the antecolic group (A group, n = 58) and the vertical retrocolic group (VR group, n = 58).

All patients underwent detailed pre-operative physical examination with haematological and biochemical assessment including measurement of tumour markers. The indication for surgery for all patients was suspected peri-ampullary lesion on the basis of computed tomography and additional imaging studies. Patients with distant metastases or locally far advanced tumours were

judged to be inoperable. Patients with jaundice underwent preoperative endoscopic or percutaneous transhepatic biliary drainage to decrease their serum bilirubin level. Pre-operative diabetes mellitus was assessed by the serum haemoglobin A1c level, fasting plasma glucose level, random glucose level and the oral glucose tolerance test. All patients except those with established diabetes mellitus were referred for oral glucose tolerance testing.

Prior to the surgeries, equal numbers of envelopes for an antecolic or a vertical retrocolic duodenojejunostomy were sequentially prepared in a blinded fashion to rule out any influence of bias in the choice of reconstruction technique during surgery.

The same team of surgeons performed all operations. The area resected during the PPPD included the gallbladder, common hepatic duct, pancreas head, duodenum (except the first portion) and 10 cm of the proximal jejunum. Lymph nodes in the hepatoduodenal ligament and those surrounding the common hepatic artery, peripancreatic tissue and the right side of the superior mesenteric artery were dissected. If necessary, combined portal vein resection or dissection of paraaortic lymph nodes was performed to accomplish a complete tumour resection. The duodenum was freed from the surrounding tissue and transected approximately 2-4 cm distal to the pyloric ring. The right gastric artery was divided at its origin in all patients. The lesser omentum close to the liver was dissected while preserving the vagus nerve to allow free movement of the stomach. These procedures allowed the stomach and the duodenum to be mobilized to the left in a straight, vertical manner. In reconstruction, the proximal jejunum was brought through the right side of the transverse mesocolon via the retrocolic route. An end-to-side pancreaticojejunostomy was performed with duct-to-mucosa anastomosis. A hepaticojejunostomy was performed 5-10 cm distal to the pancreaticojejunostomy. Then, an end-to-side duodenojejunostomy was performed about 50 cm distal to the hepaticojejunostomy based on randomization to either the antecolic or vertical retrocolic route. For vertical retrocolic duodenojejunostomy, the left side of the transverse mesocolon (to the left of the middle colic vessels) was opened, and the stomach and duodenum were brought down in a straight, vertical manner. The retrocolic duodenojejunostomy was performed at the caudal side of the transverse mesocolon, and the gastric antrum was fixed to the transverse mesocolon with several sutures. A Braun anastomosis was added in both reconstruction procedures. A schema of the reconstruction techniques used for both procedures is shown in Fig. 2. Two (or three) closed drains were placed around the pancreatic and biliary anastomoses. A pancreatic drainage tube and a biliary drainage tube were placed at the pancreatic duct and hepatic duct, respectively, and were exteriorized through the jejunal limb. A feeding tube was not placed in any of the patients.

All patients received prophylactic antibiotics for 2 to 3 days post-operatively. The patients were given epidural anaesthesia for 4–5 days post-operatively and/or adequate analgesia, and early ambulation was encouraged. The general protocol for patient care

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