

Reviewer 1

Comments to authors

Authors studied superiority between plastic stent (PS) and nasobiliary catheter (NBC) for preoperative drainage in a retrospective setting. This attempt is clinically valuable and the study is well-organized. Their results and conclusions are simple and reasonable. However, there are some questions for their results and requests for their analysis.

Major comments:

1. In definitions, PS/NBC dysfunction includes occlusion of PS/NBC and cholangitis. What is the definition of “cholangitis”? And, how was the stent occlusion diagnosed? Did the authors decide any diagnostic factors for stent occlusion? What differences is it to “insufficient drainage”?

(Reply)

As the reviewer comments, it was difficult to distinguish stent occlusion, cholangitis or insufficient drainage because of their overlap and disconfirmation, and thus, we did not refer to each event and analyzed as one category as stent dysfunction. We added next sentence in the *Definitions* of the manuscript and legend in Table 2; “Occlusion or cholangitis” included jaundice or re-elevation of liver enzyme with or without fever-up, and fever-up without other causes even if no elevation of liver enzyme; “Insufficient drainage” included persistent liver dysfunction or limited improvement of the elevated liver enzyme, which is sometimes difficult to distinguish from other causes of liver dysfunction.

2. Basically, pancreatic cancer and bile duct cancer are different diseases. So, please perform additional analysis of the efficacy of drainage, separated into pancreatic cancer and bile duct cancer. It is fine to show the results even in the supplementary tables.

(Reply)

As the reviewer's comment, we performed additional analyses of the efficacy of drainage in patients with biliary tract cancer and pancreatic cancer and added it in the supplementary tables. There was no additional difference in the result of each subgroup.

3. Why was scheduled PS replacement performed in so many 94 patients? They could not accept PS from the initial drainage? Moreover, this designed PS replacement was performed in a median of 8.4 days. And the incidence curve of PS/NBC dysfunction was separated at about 8 days between PS and NBC in figure 2. Is there a relationship in these?

(Reply)

As this was a multicenter retrospective study, the schedule of replacement of NBC to PS was not prescribed. In some participating hospitals, they made it a rule to place a NBC as the initial drainage and to replace them with a PS 4-10 days later when the jaundice was improving. So more than half cases in NBC group were censored by 10 days, which was shown as the number at risk in Figure 2. To avoid the effect of so many censored cases, competing analysis was applied instead of Kaplan-Meier analysis in this study.

Minor comments:

1. Some parameters and statements are missing in Table 1 and 2. Eg. "Others", (percentages) in Table 1, severities of pancreatitis and percentages in Table 2.

(Reply)

We corrected Table 1 and 2 according to the reviewer's comment.

2. Why did authors define the jaundice as 3.0 mg/dL? Did the subjects not include < 3.0 mg/dL? Did the patients with 2.9 mg/dL of T-bil not received EBD?

(Reply)

The jaundice was defined as 3.0 mg/dL by using the application with modifications of Child-Pugh Classification for cirrhotic patients, which was clinically used as one of the indications for surgery. There were 325/419 patients with T.Bil \geq 3.0 mg/dL, which was shown in the 1st paragraph of the result and in Table 5. Other patients of less than 3 mg/dL also underwent EBD to resolve other elevated liver enzyme and/or prevention of jaundice during long waiting time for surgery, to obtain histological confirmation by biopsy or brushing cytology from the bile duct, or to diagnosis of tumor extent, especially in patients with bile duct cancer.

Reviewer 2**Comments to authors**

Thank you for submit your manuscript to our journal. The authors described clinical impact of ENBD drainage as preoperative biliary drainage. I agree your

results. But results are not so novel in Japan, however, this study included a large number of patients. Therefore, this manuscript has some advantages of publication in World J Gastroenterol if revised version is well corrected. Author described that 'Patients who were diagnosed with distal biliary obstruction'. However, in your study, involvement of the intrahepatic bile duct patients was included. Why? Only distal biliary obstruction patients were included? This result may be based on including intrahepatic bile duct cancer. I cannot agree this point. Because ENBD was performed in many biliary tract cancer patients in Japan, patient's selection bias may occur in your study. In addition, biliary cancer has biologically, clinically differences from pancreatic cancer. Therefore, biliary tract cancer should be excluded in your study.

(Reply)

Patients with intrahepatic bile duct stricture is excluded in this study, which is described as "biliary stricture located ≥ 2 cm downstream from the hilar bifurcation" in the definitions of MATERIALS AND METHODS of the manuscript. We are afraid that the reviewer has misread "intraPANCREATIC bile duct" in Table 1 as "intraHEPATIC bile duct".

As the reviewer's comment, we added the analysis about patients with biliary tract cancer and pancreatic cancer separately and showed in supplementary tables. There was no additional difference in the result of each subgroup.