Original Article

Efficacy of Pre-Operative Portal Vein Embolization of Biliary Neoplasm before Major Hepatectomy

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Background: Malignant biliary neoplasm is relatively common in Southeast Asia. Portal vein embolization (PVE) is a preoperative procedure to induce hypertrophy of future liver remnants. PVE can decrease the rate of post hepatectomy liver failure (PHLF).

Objective: To evaluate the efficacy of preoperative PVE of biliary neoplasm patient prior to major hepatic resection.

Materials and Methods: The study included 53 patients with biliary neoplasm planned for major hepatic resection and that underwent PVE between July 2013 and August 2019. Liver volumetry before and after PVE was analyzed. Operative procedure and post hepatectomy outcome were evaluated.

Results: Peri-hilar type cholangiocarcinoma, Bismuth-Corlette classification IIIA was the most frequent tumor. The technical success rate of PVE is 100%. Future liver remnant (FLR) volume after PVE was significantly increased from 379.1 to 460 mL ($p<0.001$). Post PVE FLR over total functional liver volume (TFLV) ratio was significantly increased from 27.8% to 34.6%($p<0.001$). The mean kinetic growth rate (KGR) per week was 7.1%. Twenty-four patients underwent subsequent hepatectomy, and two patients presented with PHLF. Twenty-nine patients (54.7%) did not undergo subsequent hepatectomy as planned due to advanced disease with 21 (72.4%) because of locally advanced cancer, peritoneal carcinomatosis, and N2 lymph nodes metastasis), four (13.8%) that refused surgical treatment, and three (10.3%) that were loss to follow-up.

Conclusion: Preoperative PVE before major hepatic resection in biliary neoplasm patients is an effective procedure to increase FLR, FLR/TFLV ratio, and provide good KGR. However, more than half of post preoperative PVE could not be obtained hepatectomy because of the progression to advanced stage of disease.

Keywords: Biliary neoplasm, Portal vein embolization, Future liver remnant, Major hepatic resection, Post hepatectomy liver failure

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Biliary neoplasm is a relatively rare and intractable disease worldwide[1,2]. Hepatectomy for this neoplasm is different from primary or metastatic hepatic cancer. There are advanced biliary surgical procedures that are complicated and often resect large amounts of hepatic tissue. The incidence of post hepatectomy liver failure (PHLF)may be as high as 10% to 20% after major hepatic resection in the high-risk patient[3] and associated with a very high mortality rate[4].

Portal vein embolization (PVE) is an interventional radiology procedure first devised in 1984 by Makuuchi et al[5]. PVE is now performed widely as a safe and effective preoperative intervention to induce hypertrophy of future liver remnant (FLR) and decrease the incidence of PHLF[4]. This procedure redirects portal blood to non-embolized segments or hepatic segments of the FLR resulting in hypertrophy[6]. At present, PVE is being used as standard preoperative management in patients with inadequate FLR for the prevention of PHLF.

Currently, the efficacy of preoperative PVE before major hepatic resection in biliary neoplasm patients has been described in several reports[1,5,7]. In Thailand, especially in the Northeastern region, which had the highest incidence rate of cholangiocarcinoma (CCA) in the world[8], there are a few studies of PVE in biliary neoplasm[9]. The present study aimed to

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evaluate the efficacy of preoperative PVE in biliary neoplasm patients who underwent major hepatic resection.

Materials and Methods

Patient population

The present study was approved by the local institutional review board for ethical issues. The inform consent was waived due to this was a retrospective study. All patients who underwent preoperative PVE with computed tomography (CT) to evaluate hepatic volume before and after PVE between July 2013 and August 2019 were included. Eighty-five patients underwent preoperative PVE for biliary neoplasm. Thirty-two patients were excluded because of inadequate pre- and post-PVE hepatic volumetric data. Therefore, 53 patients were included in the present study.

Portal vein embolization

PVE was indicated when inadequate FLR volume as following[10,11]:

1. Normal liver or indocyanine green retention test (ICG R15) of less than 10% with FLR less than 30%
2. Cirrhotic liver:
   1) if ICG R15 of 10% to 20% with FLR less than 40%
   2) if ICG R15 of more than 20% with FLR less than 50%

PVE was performed at least two to four weeks before the schedule for hepatectomy. In jaundice patients, PVE was performed after the total bilirubin concentration had decreased to less than 5 mg/dL following biliary drainage.

The portal vein was accessed by ultrasound-guidance with a transhepatic approach under local anesthesia. Portogram was performed to evaluate the anatomy of the portal system. When extended right hepatectomy or right hepatectomy was planned, right portal vein (RPV) with or without medial segmental branch of left portal vein (LPV) was embolized. When extended left hepatectomy or left hepatectomy was planned, LPV with or without anterior segmental branch of RPV was embolized. Polyvinyl alcohol (Contour SE, Boston Scientific), trisacryl-gelatin (Embosphere, Merit Medical Systems), fibered platinum coil (VortX-18, Boston Scientific; MicroNester, Cook) and N-butyl-cyanoacrylate (NBCA) were used for embolization depending on operator preference.

Post PVE procedure complications, including minor complications such as fever, transient elevation of transaminase, abdominal discomfort or pain, nausea and vomiting, and ileus, were recorded from medical records. Major complications including massive portal vein thrombosis, non-target embolization, cholangitis, liver hematoma, and intra-abdominal bile leakage were also recorded[12].

Liver volumetry

A 5 mm or less slice thickness CT was obtained in multiphase, including non-contrast, late arterial, and portal phases. On individual slices, the whole liver, tumor, major hepatic vessels, dilated bile duct, and the FLR was delineated with a handheld cursor using Phillips IntelliSpace Portal CT Liver Analysis application version 7.0.1.20482 (10 July 2015) on department workstation (Figure 1). The portal phase was a primary usage image. Post PVE CT scan was scheduled two to six weeks after PVE. Data were reviewed individually in both pre and post PVE images.

Total functional liver volume (TFLV) was the calculated total hepatic volume subtracted by the tumor volume. FLR was defined as the portion that remained after the proposed hepatectomy. FLR/TFLV ratio was calculated. KGR was calculated by the following formula: KGR=percentage increased FLR/TFLV ratio after PVE at the first post-PVE CT volume assessment (%) ÷ time elapsed since PVE (weeks) at the first post-PVE CT volume assessment[13].

Patient outcome

The operative procedure, operative time, post-operative mortality rate, length of hospital stay, and precluding surgery were reviewed. PHLF was defined as an increasing international normalized ratio (INR) and concomitant hyperbilirubinemia on or after post-operative day 5 excluding other causes. Based on the authors' laboratory value, increase INR was defined as greater than 1.2, and hyperbilirubinemia was defined as total bilirubin (TB) greater than 1.5 mg/dL. In patients with pre-operatively increased INR or increased serum TB, PHLF was defined by an increasing INR and increasing serum TB on or after post-operative day 5 compared with the values of the previous day[14].

Statistical analysis

All data were analyzed using IBM SPSS Statistics, version 19.0.2 (IBM Corp., Armonk, NY, USA). A descriptive statistic was used to describe patient demographic data. Categorical data were

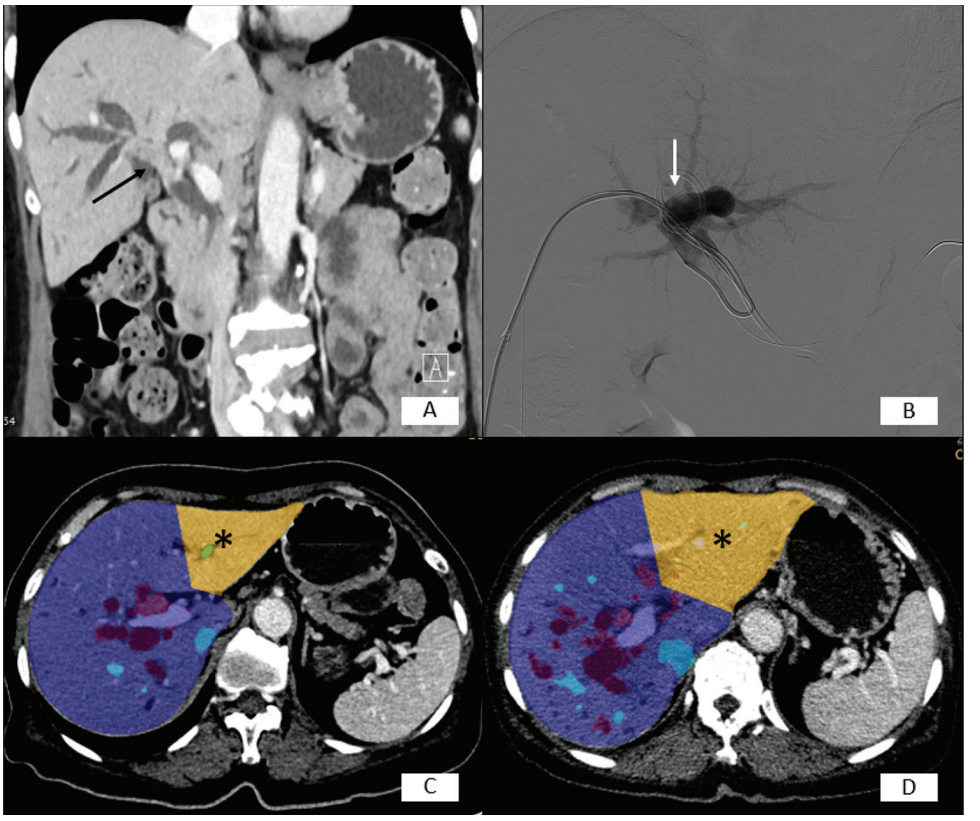


Figure 1. A 65-year-old female patient with perihilar type cholangiocarcinoma (CCA), Bismuth-Corlette type IIIA, planned for extended right hepatectomy. (A) CT scan upper abdomen shows extension of perihilar CCA (arrow). (B) Portogram after right PVE shows occlusion of right portal vein with patent left portal vein (arrow). (C) CT volumetric program contouring lateral segment of left hepatic lobe as FLR (*) for calculated volume. (D) CT volumetric program after right PVE 30 days, contouring lateral segment of left hepatic lobe (*) shows hypertrophy of FLR (FLR increase 77.1%).

presented as numbers and percentages. Continuous data were presented as mean, standard deviation, median, and range. Comparison between TFLV and FLR volumes before and after PVE would be performed by either paired t-test or Wilcoxon Signed-Rank test, as appropriated. The association between volumetric parameters and demographic data was used in an independent sample t-test. Correlation test was assessed using either Pearson or Spearman correlation, as appropriated. A p-value of less than 0.05 was considered statistically significance in all statistical tests.

Ethical approval

All procedures performed in reports involving human participants were in accordance with the ethical standards of the institutional and national research committee and the 1964 Helsinki declaration and its later amendments or comparable ethical standards. For this type of report, formal consent is not required.

Office of The Khon Kaen University Ethics Committee in human research KKU EC approved this study with the trial number "HE621531".

Results

Fifty-three patients underwent preoperative PVE for biliary neoplasm with pre- and post-PVE hepatic volumetric data between July 2013 and August 2019. There were 42 men (79.2%) and 11 women (20.8%) with a mean age of 62.8 years (range 43 to 82). There were six patients (11.3%) with underlying diabetes mellitus. The most frequent tumor was peri-hilar type CCA (50.9%) (Table 1). Seven patients (13.2%) had combined intra-hepatic and peri-hilar type CCA. Two patients (3.8%) had co-existing hepatocellular carcinoma (HCC) and biliary neoplasm. Bismuth-Corlette classification type IIIA was the most frequent type (17 patients, 50%) (Table 1). Preoperative biliary drainage was performed in 27 patients (50.9%).

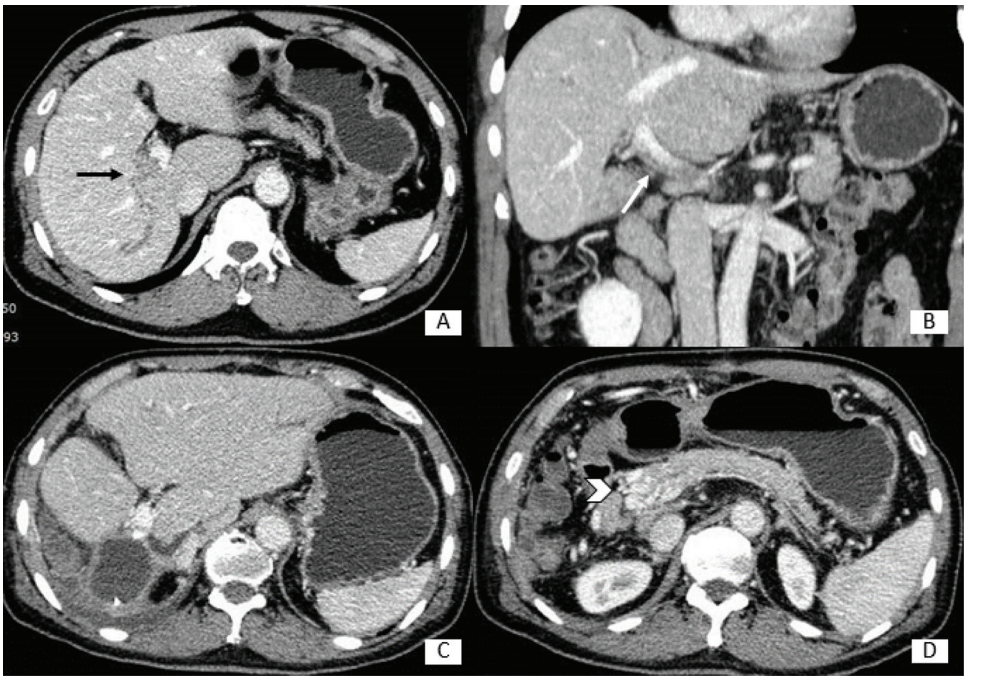


Figure 2. A 55-year-old male patient with perihilar type cholangiocarcinoma, Bismuth-Corlette type III, post right PVE. (A) and (B) CT scan upper abdomen show thrombosis of right portal vein (black arrow) and partial thrombosis of main portal vein (white arrow). (C) Two months after right hepatectomy, CT scan upper abdomen shows hypertrophy of residual left hepatic lobe. (D) Chronic thrombosis with small size of main portal vein at splenoportal confluence and cavernous transformation (arrow head).

Table 1. Types of biliary neoplasm

Biliary neoplasm	n (%)
Tumor type (n=53)	
Perihilar CCA	27 (50.9)
Intrahepatic CCA	12 (22.6)
Combined intrahepatic and perihilar CCA	7 (13.2)
IPNB	7 (13.2)
Bismuth-Corlette classification of perihilar CCA (n=34)	
Type I	2 (5.9)
Type II	3 (8.8)
Type IIIA	17 (50)
Type IIIB	4 (11.8)
Type IV	8 (23.5)

CCA=cholangiocarcinoma; IPNB=intraductal papillary neoplasm of the bile duct

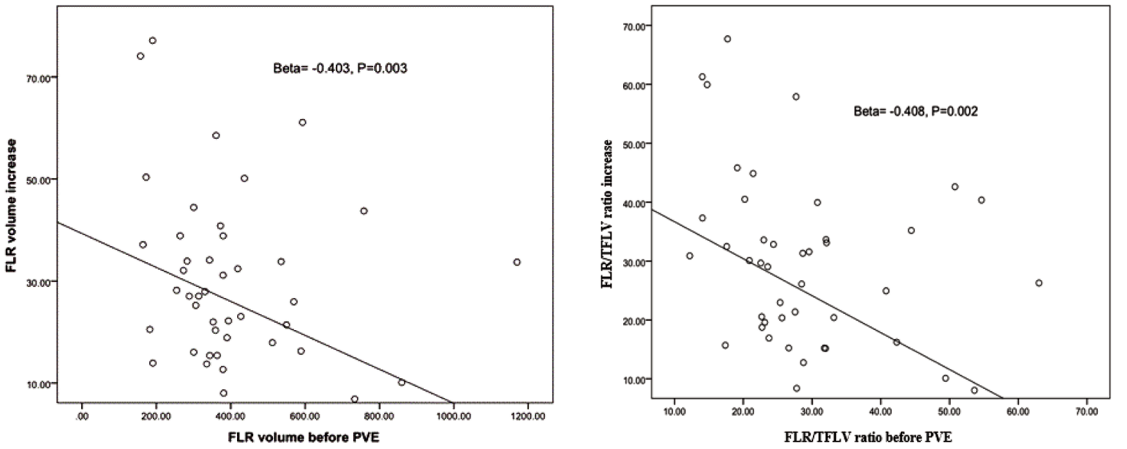
Table 2. PVE-related complications

Complications	n (%)
Minor complications	37 (75.8)*
Transient fever	34 (51.5)
Transient elevation of hepatic enzymes	1 (1.5)
Abdominal discomfort	14 (21.2)
Nausea and vomiting	1 (1.5)
Major complications	3 (5.7)
Cholangitis	1 (1.9)
Partial main portal vein thrombosis	2 (3.8)
Mortality	0 (0.0)

* Some of the cases occur a combination of minor complications

The technical success rate of PVE was 100%. Most patients were performed with the ipsilateral portal vein approach (86.8%). Most patients underwent RPV embolization (n=47, 88.7%). Four patients underwent LPV with an anterior segmental branch of RPV embolization. Two patients underwent LPV embolization and RPV with the medial segmental branch of LPV embolization. PVA size range between 150 to 250 and 710 to 1,000 microns was used for embolization in most of the cases (52 patients, 98.1%). NBCA was used for embolization in one case. Coils were used as additional embolic material in four cases (7.5%).

After PVE, three patients developed major complications, where two developed partial main portal vein thrombosis (Figure 2) and one developed cholangitis (Table 2). All three underwent major



(A) (B)

Figure 3. Graph show superior growth in patients with small FLR volume and small FLR/TFLV ratio, which is represented by negative correlation between FLR volume increase and FLR volume before PVE (A) and between FLR/TFLV ratio increase and FLR/TFLV ratio before PVE(B).

Table 3. Change in CT volumetry after PVE

CT volumetric parameters	Pre-PVE	Post-PVE	p-value
FLR volume (mL); median (IQR)	379.1 (305.9 to 539.0)	460 (378.4 to 655.6)	<0.001
TFLV volume (mL); median (IQR)	1,392.7 (1,149.0 to 1,657.4)	1,316.9 (1,094.1 to 1,642.7)	0.220
FLR increase (%); mean±SD	-	24.3±19.6	-
FLR/TFLV ratio (%); median (IQR)	27.8 (22.72 to 40.76)	34.61 (29.84 to 46.95)	<0.001
FLR/TFLV ratio increase (%); mean±SD	-	23.6±18.5	-
KGR/week (%); mean±SD	-	7.1±5.6	-

CT=computed tomography; PVE=portal vein embolization; FLR=future liver remnant; TFLV=total functional liver volume; KGR=kinetic growth rate; IQR=interquartile range; SD=standard deviation

hepatic resection later without PHLF, and no procedure-related death occurred.

The median interval between pre-and post-PVE CT hepatic volumetry was 36 days (P25=10, P75=45). Post-procedural CT assessment were performed after PVE in median 24 days (range 12 to 44). There was a significant increase in FLR volume after PVE, from 379.1 to 460 mL (p<0.001) and FLR/TFLV ratio after PVE, from 27.8% to 34.6% (p<0.001) (Table 3). Mean FLR increase was 24.3±19.6% and FLR/TFLV ratio increase was 23.6±18.5%. KGR per week was 7.1±5.6% per week. Negative correlation was observed between FLR volume increase and FLR volume before PVE (beta –0.403, p=0.003) and between FLR/TFLV ratio increase and FLR/TFLV ratio before PVE (beta –0.408, p=0.002) (Figure 3).

Underlying diabetes mellitus, chronic hepatitis, and history of preoperative biliary drainage did not show any significant effect for FLR increase, FLR/TFLV ratio increase, and KGR after PVE (Table 4).

Twenty-four patients (45.3%) underwent subsequent hepatectomy, including 12 right extended hepatectomy, nine right hepatectomy, two left extended hepatectomy, and one left hepatectomy. Twenty-nine patients (54.7%) did not undergo subsequent hepatectomy as planned due to advanced disease with 21, 72.4% that had locally advanced cancer, peritoneal carcinomatosis and N2 lymph nodes metastasis, four (13.8%) that refused surgical treatment, and three (10.3%) that were loss to follow-up.

PHLF occurred in two cases (8.3%). The patients with PHLF had lower FLR increase, FLR/TFLV ratio increase, and KGR per week than those who did not have PHLF. No post-operative mortality occurred.

Discussion

The most current CCA is perihilar type, usually aggressive, and needs major hepatic resection for curative treatment[15]. The rate of PHLF without PVE in CCA may high as 10% to 20%[3]. Many previous

Table 4. Demographic data affecting volumetric parameters

	Yes; mean±SD	No; mean±SD	p-value
Underlying DM (%) (n=6)			
FLR increase	31.7±28.3	23.3±18.4	0.509
FLR/TFLV ratio increase	29.1±24.2	22.9±17.8	0.566
Kinetic growth rate/week	9.7±6.5	6.8±5.5	0.343
Chronic hepatitis (%) (n=5)			
FLR increase	23.9±17.1	24.3±20.0	0.965
FLR/TFLV ratio increase	28.6±21.1	23.1±18.4	0.600
Kinetic growth rate/week	7.1±4.6	7.1±5.8	0.991
Pre-operative biliary drainage (%) (n=27)			
FLR increase	25.3±21.9	23.2±17.3	0.687
FLR/TFLV ratio increase	22.9±19.4	24.3±17.8	0.787
Kinetic growth rate/week	7.0±6.3	7.3±5.1	0.864

DM=diabetic mellitus; FLR=future liver remnant; TFLV=total functional liver volume; SD=standard deviation

studies show that preoperative PVE is significant to induce hypertrophy of FLR and clinical impact to decrease the rate of PHLF[1,8,14].

The present study showed a significant increase in FLR volume and FLR/TFLV ratio after PVE. The initial FLR volume and FLR/TFLV ratio were predictive factors for the degree of increase in FLR and FLR/TFLV ratio. The patients with relatively low initial FLR and low FLR/TFLV ratio had a greater degree of increase FLR and FLR/ TFLV ratio after PVE. These results agree with the previous studies[16,17]. The association between underlying diabetes mellitus, chronic hepatitis, and degree of increase in FLR and FLR/TFLV ratio were not significant in the present study, but this may be due to the small sample size.

Previous studies reported that high KGR per week correlated with good post-hepatectomy outcome[13,18]. A KGR per week of 2% or more correlated with a significantly decrease incidence of PHLF[13]. Patients who developed PHLF had a KGR per week in the range of 7.0% to 10.9%. This result confirms that the KGR per week is not the only factor that can predict PHLF. The predilection tends to be due to multiple factors such as the waiting period for hypertrophy before undergoing surgery and the complexity of the operative procedure. The degree of FLR increase, FLR/TFLV ratio increase, and KGR per week correlation with the PHLF rate was not statistically significant in the present study. It is inconsistent with previous studies[18], which is probably due to a small number of patients in the present study, which was 53 patients versus 153 patients from Leung et al[18].

PVA was the most used embolic agent in the present study, with additional coil embolization in some cases. There was only one case that used NBCA as the embolic agent. A previous systematic review showed that NBCA tends to be the more powerful embolic agent, inducing an increase in FLR ranging from 27.5% to 69.4% compared to PVA associated with coils or vascular plug in the range of 24.3% to 26.4%[12]. While NBCA is a more powerful embolic agent to induce FLR hypertrophy, it has a steep learning curve and is more difficult to master for safe catheterization in non-targeted embolization. The present study demonstrates that PVA with or without associated coil is also effective in inducing adequate FLR before major hepatic resection.

The authors performed right or left PVE in most cases. Trisegmental PVE is rarely mentioned in literature[12]. Nagino et al reported that the right trisegmental PVE significantly increased the FLR volume compared with right PVE, and the PHLF rate was 14.3%[19]. However, the authors observed a lower PHLF rate in the present study institute. The PVE-related major complication rate is within an acceptable range[11]. The PVE-related minor complication seems slightly higher than literature. The transient fever rate is 51.5% versus 36.9% from van Lienden et al[12].

The rate of unresectable tumors from the present study was higher than in previous studies, ranging from 12.0% to 55.0%[1,7,20,21]. Ebata et al and Nagino et al observed a rate of unresectable CCA tumors of 12.0% to 17.3%, but they resected tumors in patients with a more advanced disease stage of M1[1,7]. The institutional surgeon strategy will be undergoing

curative resect patients without evidence of local advance, N2 lymph node metastasis, and M1 disease. The present study shows the same results as Anaya et al and Mansour et al, who found an unresectable rate of CCA is range 20% to 55%[20,21]. Most patients with unresectable tumors in the present study were considered unresectable due to advanced disease. The development of early screening disease and provide health care accession are very important to detect early stages of the disease and increase the rate of resectable patients[22].

There were some limitations of the present study. First, it was a retrospective study. Second, the small patient population with adequate data for calculated hepatic volume before and after PVE limited the authors' sample size. Third, the present population had a higher unresectable rate after PVE due to advanced disease. Patient selection is necessary to decrease inessential intervention. A strength of the present study was the homogeneous patient population with biliary neoplasm.

Conclusion

Pre-operative PVE in biliary neoplasm patients before undergoing major hepatic resection is an effective procedure to increase FLR, FLR/TFLV ratio, and provide good KGR for decrease PHLF. However, the majority of the patients could not be performed a hepatectomy because of the progression of the underling malignant disease.

What is already known on this topic?

Pre-operative PVE is a highly effective procedure to increased FLR, FLR/TFLV ratio and decreased PHLF.

What this study adds?

This study found very good outcome of PVE to induce FLR, FLR/TFLV and could provide less post-operative liver failure after surgery. However, less than 50% of post pre-operative PVE cases could not be performed surgical hepatectomy procedure due to more progression into advanced stage of the underlying malignancy disease.

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Conflicts of interest

The authors declare no conflict of interest.

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