









Predictive Factors for Symptomatic Dislodgement of Percutaneous Transhepatic Biliary Drainage Catheter in Patients with Malignant Biliary Obstruction

악성 담관 폐쇄 환자에서 경피경간 담도 배액술의 유증상 이탈 발생의 예측 인자

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Purpose To evaluate the factors that predict symptomatic dislodgement of a percutaneous transhepatic biliary drainage (PTBD) catheter in patients with malignant biliary obstruction.

Materials and Methods This retrospective study included 572 patients with malignant biliary obstruction who underwent 733 PTBD catheter insertions between January 2010 and February 2015. The duration of catheter placement, approach site, location of the catheter tip, insertion angle, presence of a closed-loop pigtail, and tube diameter were evaluated.

Results During the follow-up period, 224 PTBD catheter dislodgements (30.56%) were observed in 157 patients. Among them, 146 (19.92%) were symptomatic. The mean duration from catheter insertion until dislodgement was 32 days (range: 1–233 days). Male (odds ratio [OR]: 1.636, 95% confidence interval [CI]: 1.131–2.367, $p = 0.009$), right-sided approach (OR: 1.567, 95% CI: 1.080–2.274, $p = 0.018$), increased insertion angle (OR: 1.015, 95% CI: 1.005–1.026, $p = 0.005$), and incomplete closed-loop pigtail formation (OR: 1.672, 95% CI: 1.098–2.545, $p = 0.016$) were independent factors predictive of symptomatic dislodgement of a PTBD catheter.

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Conclusion Factors predictive of symptomatic catheter dislodgement included male sex, a right-sided approach, increased insertion angle, and incomplete closed-loop pigtail formation.

Index terms Biliary Tract Cancer; Catheter; Drainage; Jaundice, Obstructive

INTRODUCTION

Biliary obstruction is caused by several conditions, including benign and malignant diseases. Malignant biliary obstruction more commonly results from pancreatic adenocarcinoma and cholangiocarcinoma, whereas gallbladder carcinoma, hepatocellular carcinoma (HCC), lymphoma, and metastatic diseases that infiltrate the pancreatic head and common bile duct can also cause biliary obstruction (1-4). Malignant biliary obstruction results in jaundice in 70%–90% of patients and affects their quality of life and overall mortality (5).

Malignant biliary obstruction can be treated with medical therapy, surgical resection, endoscopic or percutaneous transhepatic biliary drainage (PTBD), and stent insertion (6). Curative resection is the best treatment; however, the diagnosis is often made at an advanced unresectable stage when palliative decompression remains the only option (7). PTBD is a well-established procedure with proven efficacy and relative safety for malignant biliary obstruction (8-10). However, PTBD is associated with various complications in 3%–10% of patients, ranging from puncture site pain to life-threatening conditions, including access-related, nonvascular, vascular or bleeding, catheter-related, and stent-related complications (11). Catheter dislodgement is a catheter-related complication leading to insufficient biliary drainage and decompression failure. In these cases, a secondary interventional procedure may be required to reposition the catheter. To the best of our knowledge, no previous study has evaluated the factors influencing symptomatic catheter dislodgement. This study aimed to identify the factors predictive of symptomatic dislodgement of PTBD catheters.

MATERIALS AND METHODS

STUDY POPULATION

The study design was approved by our Institutional Review Board (IRB No. KUGH 2021-10-010-001). The requirement for written informed consent was waived because of the retrospective design of this study.

Patients with malignant biliary obstruction who underwent PTBD catheter insertion at the Radiology Department of our institution between January 2010 and February 2015 were retrospectively analyzed.

During the study period, 572 patients (313 male and 259 female) with malignant biliary obstruction and an average age of 65 years (range: 43–78 years) underwent 733 PTBD catheter insertions. Two types of drainage catheters (Cook Medical, Bloomington, IN, USA; Sungwon Medical, Cheongju, Korea) were used, depending on the supply conditions. The catheters were sutured to the skin after the procedure, and every tagging suture was performed by the

operator. The underlying primary malignancies were cholangiocarcinoma ($n = 334$, 58.39%), pancreatic cancer ($n = 82$, 14.34%), HCC ($n = 47$, 8.22%), ampulla of Vater (AoV) cancer ($n = 17$, 2.97%), and metastatic biliary obstruction ($n = 92$, 16.08%).

Demographic data (sex, age, diagnosis, and duration of catheter placement) were obtained from electronic medical records. The approach site, tube diameter, and catheter tip location were recorded during each PTBD procedure. The insertion angle and presence of closed-loop pigtail formation were investigated by reviewing the fluoroscopic images obtained during each procedure. The insertion angle was determined as the angle formed by the line between the thoracolumbar spinous processes and the line connecting the puncture site in the skin to the bile duct on the fluoroscopic image.

Postprocedural complications caused by catheter dislodgement were investigated by reviewing electronic medical records and images, including US, CT and MR.

FOLLOW UP ASSESSMENT

After PTBD catheter insertion, serial abdominal radiographs were obtained in the supine position to detect and evaluate catheter dislodgement. Clinical symptoms, signs, and serum total bilirubin levels were evaluated serially.

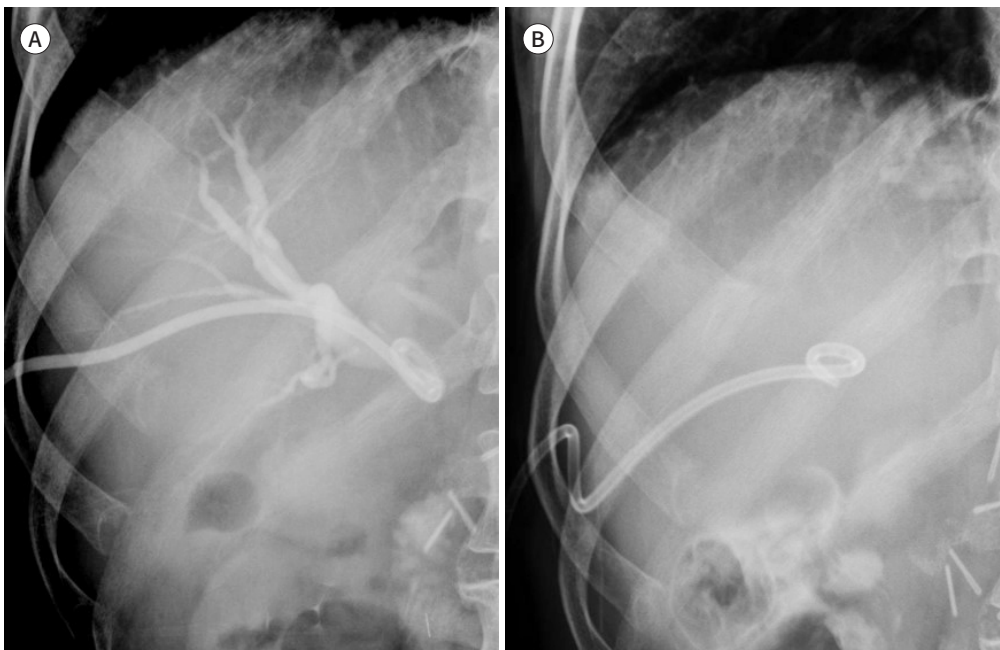
Catheter dislodgement was defined as catheter tip displacement to the ipsilateral peripheral

Fig. 1. Definition of catheter displacement. A 75-year-old male patient with cholangiocarcinoma presented with right upper quadrant abdominal pain and jaundice. He underwent PTBD catheter insertion for biliary decompression.

A. Post-procedural supine abdominal radiography shows the PTBD catheter tip located at hilar level. The catheter is inserted through the right-sided approach.

B. Follow-up supine abdominal radiography obtained 11 days after the PTBD procedure shows displacement of the catheter tip to ipsilateral peripheral bile duct more than 2.5 cm from its initial location. We defined catheter displacement as more than 2.5 cm of catheter dislodgement.

PTBD = percutaneous transhepatic biliary drainage



al bile duct by > 2.5 cm from its initial location on serial follow-up radiographs (Fig. 1). Symptomatic catheter dislodgement was defined as displacement of the catheter tip that caused catheter malfunctioning, an increase in serum total bilirubin of > 2 mg/dL, or newly developed symptoms such as jaundice or pruritus.

The postprocedural follow-up assessments were conducted until the study endpoint, defined as the exchange of the PTBD drainage catheter or when the patient underwent another biliary procedure. Serum total bilirubin levels were compared with the lowest serum total bilirubin levels measured during the study period.

STATISTICAL ANALYSIS

Categorical variables were compared using either Student's *t*-test or one-way ANOVA, as appropriate, and are presented as percentages. Continuous variables were compared using the Mann-Whitney U test and are presented as mean \pm standard deviation. Multivariate analysis was conducted using the Cox proportional hazards model to identify potential independent factors predictive of symptomatic catheter dislodgement. Variables with a *p*-value < 0.05 in the univariate analysis were included in the multivariable analysis, and the results are presented as odds ratios with 95% confidence intervals (CIs). Data were analyzed using SPSS statistical software (IBM SPSS Statistics for Windows, version 27.0. Released 2020; IBM Corp., Armonk, NY, USA). Statistical significance was defined as *p* < 0.05.

RESULTS

During the follow-up period, 224 catheter dislodgements (30.56%) were observed in 157 patients. The mean duration from catheter insertion until dislodgement was 32 days (range: 1–233 days). Among these, 146 (19.92%) in 93 patients were symptomatic, causing cholangitis, jaundice, pruritus, pain, or catheter malfunction. Of these symptomatic dislodgement cases, 21 (14.38%) occurred within three days after the procedure, and 36 dislodgements (24.66%) occurred within seven days after the procedure. A comparison of patient groups according to the presence or absence of symptomatic catheter dislodgement is summarized in Table 1.

Of the 146 patients in the symptomatic dislodgement group, 105 were male (71.92%), and 41 were female (28.08%). The proportion of males was significantly higher than that of females (*p* < 0.001) in the symptomatic dislodgement group.

The mean age of the symptomatic dislodgement group was 65 years and that of the asymptomatic dislodgement or non-dislodged group was 67 years. There was no significant difference in the frequency of symptomatic dislodgement according to age (*p* = 0.144).

The underlying primary malignancies in the symptomatic dislodgement and asymptomatic dislodgement or non-dislodged group were cholangiocarcinoma (64.38% and 59.45%, respectively), pancreatic cancer (6.85% and 14.48%, respectively), AoV cancer (4.11% and 2.90%, respectively), HCC (7.53% and 7.33%, respectively), and metastatic biliary obstruction (17.12% and 15.84%, respectively), with no significant differences between the groups (*p* = 0.206).

The mean duration of catheter placement in the symptomatic dislodgement group (44 days) was significantly longer than that in the asymptomatic dislodgement or non-dislodged group (22 days, *p* < 0.001).

Table 1. Comparison of Demographic and Procedural Factors

Factor	Symptomatic Dislodgement (+) (n = 146, %)	Symptomatic Dislodgement (-) (n = 587, %)	p-Value
Sex			< 0.001
Male	105 (71.92)	301 (51.28)	
Female	41 (28.02)	286 (48.72)	
Age (years)	65 (44.52)	67 (11.41)	0.144
Diagnosis			0.206
Cholangiocarcinoma	94 (64.38)	349 (59.45)	
Pancreatic cancer	10 (6.85)	85 (14.48)	
Ampulla of Vater cancer	6 (4.11)	17 (2.90)	
Hepatocellular carcinoma	11 (7.53)	43 (7.33)	
Metastatic biliary obstruction	25 (17.12)	93 (15.84)	
Duration (days)	44 (30.14)	22 (3.75)	< 0.001
Approach site			< 0.001
Right	63 (43.15)	140 (23.85)	
Left	83 (56.85)	447 (76.75)	
Insertion angle (°)	57 (39.04)	50 (8.52)	< 0.001
Location of tip			0.061
Ipsilateral IHD	55 (37.67)	151 (25.72)	
Contralateral IHD	26 (17.81)	94 (16.01)	
CHD	43 (29.45)	177 (30.15)	
CBD	21 (14.38)	151 (25.72)	
Duodenum	1 (0.68)	14 (2.39)	
Closed loop formation			0.012
+	118 (80.82)	503 (85.69)	
-	28 (19.18)	84 (14.31)	
Tube diameter			0.875
8.5F	102 (69.86)	414 (70.53)	
> 8.5F	44 (30.14)	173 (29.47)	

CBD = common bile duct, CHD = common hepatic duct, IHD = intrahepatic duct

Most drainage catheters were placed in the right biliary system (530 cases, 72.31%) than the left biliary system (203 cases, 27.69%), and the right-sided approach was used in a significantly higher proportion of the symptomatic dislodgement group (43.15%) than in the asymptomatic dislodgement or non-dislodged group (24.87%, $p < 0.001$).

The mean insertion angle of the catheter in the symptomatic dislodgement group (57 degrees) was significantly higher than that in the asymptomatic dislodgement or non-dislodged group (50 degrees, $p < 0.001$).

In the symptomatic dislodgement group and asymptomatic dislodgement or non-dislodged group, the catheter tip was placed in the ipsilateral intrahepatic duct (IHD) (37.67% and 25.72%, respectively), contralateral IHD (17.81% and 16.01%, respectively), common hepatic duct (29.45% and 30.15%, respectively), common bile duct (14.38% and 25.72%, respectively), or duodenum (0.68% and 2.39%, respectively); there was no significant difference between

the groups ($p = 0.061$).

A significantly lower proportion of the symptomatic dislodgement group presented with a closed-loop formation (80.82%) than the asymptomatic dislodgement or non-dislodged group (85.69%, $p = 0.012$).

An 8.5 French tube was inserted more frequently than a catheter thicker in both the symptomatic dislodgement group (69.86%) and the asymptomatic dislodgement or non-dislodged group (70.53%); there was no significant difference between the groups ($p = 0.875$).

The results of the Cox proportional hazards model for the predictive factors of symptomatic catheter dislodgement are summarized in Table 2. The Cox proportional hazard model showed that male (odds ratio [OR]: 1.636, 95% CI: 1.131–2.367, $p = 0.009$), a right-sided approach (OR: 1.567, 95% CI: 1.080–2.274, $p = 0.018$), increased insertion angle (OR: 1.015, 95% CI: 1.005–1.026, $p = 0.005$), and incomplete closed loop pigtail formation (OR: 1.672, 95% CI: 1.098–2.545, $p = 0.016$) were independent factors predictive of symptomatic dislodgement of a PTBD catheter.

Symptomatic catheter dislodgement was managed with PTBD exchange ($n = 137$, Fig. 2) or stent insertion ($n = 9$). After the secondary intervention, all patients showed improvement in clinical symptoms and a decrease in serum bilirubin levels, except for three patients who died

Table 2. Cox Proportional Hazard Model for Factors Predictive of Symptomatic Catheter Dislodgement

	Odds Ratio (95% Confidence Interval)	<i>p</i> -Value
Sex (male)	1.636 (1.131–2.367)	0.009
Right-sided approach	1.567 (1.080–2.274)	0.018
Increased insertion angle	1.015 (1.005–1.026)	0.005
Incomplete closed loop pigtail formation	1.672 (1.098–2.545)	0.016

Fig. 2. An 80-year-old male patient who had malignant biliary obstruction due to pancreatic cancer.

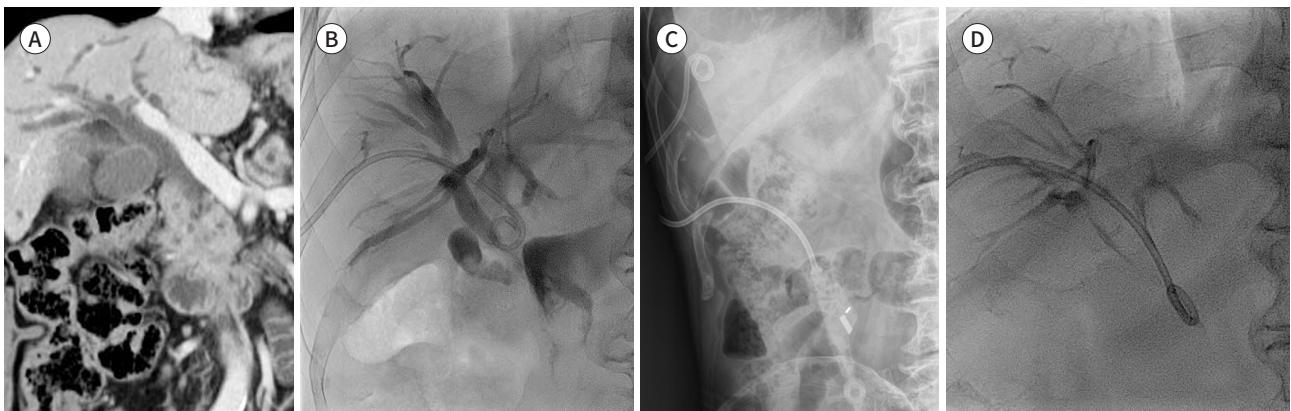
A. A preprocedural, coronal, portal venous phase CT image shows a low-density mass in the pancreatic head with upstream dilatation of the CBD and both intrahepatic ducts.

B. Fluoroscopic image obtained during the PTBD procedure shows a drainage catheter inserted through the right-sided approach, with the tip located at the hilar portion.

C. Follow-up abdominal radiograph obtained 80 days after PTBD catheter insertion shows dislodgement of the catheter. The serum total bilirubin level increased to 2.63 mg/dL, and symptoms of cholangitis, including jaundice, developed.

D. Fluoroscopic image during the PTBD exchange shows a drainage catheter inserted through the right-sided approach with the tip located at the CBD. After the catheter exchange, the serum total bilirubin level decreased to 1.8 mg/dL, and patient symptoms improved.

CBD = common bile duct, PTBD = percutaneous transhepatic biliary drainage



due to progression of the underlying disease. The mean serum bilirubin level was 8.24 mg/dL before the secondary intervention and decreased to 4.91 mg/dL after management ($p < 0.001$).

DISCUSSION

PTBD is a safe and effective procedure for biliary decompression. However, it is associated with several major and minor complications. Significant drainage-related complications in PTBD have been reported in up to 40% of patients (12). Previous studies have shown that catheter dislodgement is a common complication and major cause of cholangitis (12). Although physical dislodgement of the catheter is the most common cause of catheter dislodgement, spontaneous dislodgement or migration due to respiratory motion or movement during normal daily activities can also occur (13, 14). The PTBD catheter can be stabilized using a tagging suture to the skin, an internal retention pigtail loop, balloon catheter, catheter with an anchor system, additional external fixation devices, or tape (5, 13). Sarwar et al. (15) reported that re-admission after primary biliary drainage is common and that the majority of unplanned readmissions are drain related. Among unplanned interventional radiology-related readmissions, 16% were related to periprocedural complications, and 51% were considered preventable.

In the present study that included 733 PTBD procedures, we analyzed factors predictive of symptomatic dislodgement of PTBD catheters. To the best of our knowledge, no previous report has analyzed the rate of dislodgement with clinical significance, such as patient symptoms or elevated serum bilirubin levels, including various demographic factors. In this study, male sex, right-sided approach, increased insertion angle, and incomplete closed-loop formation of the pigtail were predictive factors for symptomatic catheter dislodgement.

In the symptomatic dislodgement group, the proportion of males was significantly higher than that of females. This result can be attributed to sex differences in breathing movements and patterns. Several previous studies have reported fewer abdominal movements during respiration in females than in males (16-18). During respiration, the movement of the rib cage makes a greater contribution in females, while in males, the movement of the diaphragm has a greater involvement (16-18).

In addition, we found that a right-sided approach was an independent predictive factor for symptomatic catheter dislodgement. Although the approach side can vary based on operator preference, patient anatomy, and indications, the right-sided approach is known to be a relatively anatomically favorable site for any subsequent intervention and has a larger drainage catchment than the left side (19). However, the right-sided approach has a higher risk of catheter dislodgement due to the constant movement of the drainage catheter in the intercostal space during respiration (8). In addition, the percutaneous route through the right side is straighter and smoother than that through the left side when the apparatus is inserted into the bile duct (7). Right-sided catheters placed at the lower aspect of the rib cage are more prone to dislodgement because of the relatively higher degree of subcutaneous thickness and pannus mobility compared to the left-sided subxiphoid approach or a higher or more anterior approach from the right side (13). In contrast, a recent study reported that right- and left-sided PTBD catheter insertion in patients with malignant biliary obstruction did not differ significantly in technique, safety, radiation dose, success rate, or quality of life (20).

In the present study, the mean insertion angle was significantly greater in the symptomatic dislodgement group. However, we measured the insertion angle on fluoroscopic images, which do not reflect the anteroposterior angle that can be measured on lateral images. We found a statistically significant difference between symptomatic dislodgement and insertion angle in the univariate analysis ($p < 0.001$); however, the calculated odds ratio in the multivariate analysis was 1.015, which was relatively low. Thus, this result shows a relatively weak association between symptomatic dislodgement and the insertion angle.

Incomplete closed-loop pigtail formation was a predictive factor for symptomatic dislodgement in this study. Closed-loop formations are known to be effective in preventing accidental catheter dislodgement and securing the stability of the inserted catheter and are now used routinely in most interventional radiology procedures that require drainage. Various anchor systems can be applied, and a previous study showed that a balloon catheter or a catheter with an outer sheath is useful for preventing catheter dislodgement (8).

In this study, age, primary diagnosis, catheter tip location, and tube diameter showed no significant relationships with symptomatic dislodgement. A previous study on PTBD catheter dislodgement in relation to puncture points in the bile duct reported that drainage from the bile duct of the anterior inferior segment was associated with a higher risk of dislodgement than drainage from the bile duct of the posterior inferior or anterior superior segments. In addition, the peripheral bile duct branch of the lateral inferior segment is associated with a higher risk of dislodgement than the main bile duct branch of the lateral inferior segment (8). Another study in 2015 reported that the bile ducts of the posterior and lateral inferior segments were preferable for right- and left-sided approaches to PTBD catheter placement, respectively, because the distance between the skin and puncture site in the bile duct was short, and the running course of the target bile duct was mostly straight from the hepatic hilum to the peripheral puncture site (21). Therefore, we expected the location of the catheter tip to be associated with catheter dislodgement due to the length of the intraductal catheter or the peripherality of the catheter; however, the location of the catheter tip was not statistically significant in this study.

In percutaneous drainage procedures, a large-bore catheter can be helpful in the temporary treatment of pericatheter leakage, drainage of thick fluid, and recurrent catheter obstruction (13). A previous study revealed that a large-bore chest tube drain was less prone to displacement than a smaller tube but was associated with a higher rate of complications when managing spontaneous pneumothorax (22). Therefore, we hypothesized that a large-diameter catheter might help prevent catheter dislodgement. However, catheter diameter had no statistically significant relationship with catheter dislodgement.

Secondary intervention procedures following symptomatic catheter dislodgement were effective in most patients except three who died due to progression of their underlying disease. Direct reinsertion through the original cutaneous puncture site is feasible because a granulating transparenchymal track forms after 7–10 days of catheter drainage, and the track remains open for 48–72 hours (23).

This study has several limitations. First, owing to the retrospective design of the study, selection bias could not be prevented. Second, as a single-institution study, the results may have been related to institutional practices, supplies, or the individual experiences of interventional

radiologists. Further studies in other institutions are required to validate our results. Third, due to the long study period, confounders related to changes in medical practice or patient population might have affected our results. Fourth, the insertion angle measured in this study did not reflect the anteroposterior angle. Therefore, the values measured in this study may not adequately reflect true insertion angles. Fifth, this study dichotomized the approach site for PTBD catheter insertion into the right and left sides, without segmental categorization. However, as previous studies have revealed, PTBD procedures in each segmental intrahepatic duct can differ significantly from one another.

In conclusion, catheter dislodgement appears to be a common complication of PTBD and may result in several symptoms or elevated serum total bilirubin levels owing to inadequate biliary drainage. Factors predictive of symptomatic catheter dislodgement include a right-sided approach, increased insertion angle, and incomplete closed-loop pigtail formation.

Author Contributions

Conceptualization, Y.H.J.; data curation, Y.H.J., Y.J.H.; formal analysis, Y.H.J.; methodology, Y.J.H.; software, Y.H.J.; supervision, P.J.G., Y.J.H.; validation, P.J.G., J.G.S., S.K.L., P.H.J., Y.J.H.; writing—original draft, Y.H.J.; and writing—review & editing, Y.H.J.

Conflicts of Interest

The authors have no potential conflicts of interest to disclose.

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악성 담관 폐쇄 환자에서 경피경간 담도 배액술의 유증상 이탈 발생의 예측 인자

유희정¹ · 박정구¹ · 정규식² · 서광일³ · 박현준³ · 윤종혁^{1*}

목적 악성 담관 폐쇄 환자에서 경피경간 담도 배액술을 시행할 때 유증상 이탈을 유발하는 예측 인자에 대해 연구를 진행하고자 한다.

대상과 방법 2010년 1월부터 2015년 2월까지 572명의 악성 담관 폐쇄 환자에서 시행한 733건의 경피경간 담도 배액술을 대상으로 후향적 연구를 시행하였다. 카테터의 거치 기간, 접근 위치, 카테터 팁의 위치, 삽입 각도, 피그테일 루프의 유무, 도관 직경을 평가하였다.

결과 추적관찰 기간 동안 157명의 환자에서 224건(30.56%)의 도관 이탈이 발생하였다. 그중 146건(19.92%)가 유증상 도관 이탈이었다. 배액관 이탈 발생까지의 기간은 평균 30일(범위: 1-159일)이었다. 유증상 도관 이탈은 배액관의 교체(137명) 또는 담관 스텐트 삽입(9명)을 통해 치료하였다. 남성(교차비: 1.636, 95% 신뢰구간: 1.131-2.367, $p=0.009$), 우측 접근(교차비: 1.567, 95% 신뢰구간: 1.080-2.274, $p=0.018$), 도관 삽입 각도 증가(교차비: 1.015, 95% 신뢰구간: 1.005-1.026, $p=0.005$), 불완전 피그테일 루프(교차비: 1.672, 95% 신뢰구간: 1.098-2.545, $p=0.016$)가 독립적인 경피경간 담도 배액술 도관 유증상 이탈의 예측 인자였다.

결론 유증상 이탈을 유발하는 예측인자에는 남성, 우측 접근, 도관 삽입 각도 증가, 불완전 피그테일 루프가 있다.

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