

# PRE-PROCEDURE RISK STRATIFICATION AND OUTCOMES AFTER PERCUTANEOUS TRANSHEPATIC BILIARY DRAINAGE FOR MALIGNANT OBSTRUCTION: A PROSPECTIVE SINGLE-CENTRE STUDY

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*Recent studies have identified multiple factors associated with increased mortality and morbidity in patients undergoing percutaneous biliary interventions. Although several risk stratification scales have demonstrated value in identifying high-risk patients, evidence remains limited for populations with advanced frailty and short life expectancy, where quality of life is a primary concern. This observational study aimed to replicate previously reported results using a risk stratification scale and explore additional risk factors associated with outcomes. Thirty-seven patients were assessed before the procedure using the Eastern Cooperative Oncology Group (ECOG) scale and a predefined scoring system. Mortality at 7, 30, and 90 days was determined through national registry data. While we were unable to reproduce previously published favourable results using the modified risk scale, the ECOG score was confirmed as an independent predictor of 30-day mortality ( $p = 0.028$ ). Infectious complications were common after percutaneous biliary drainage (PBD), and antibiotic prophylaxis did not influence short-term mortality. Individualised pre-procedural risk assessment is recommended for oncology patients undergoing PBD with palliative intent.*

**Keywords:** *palliative, intervention, prognosis, complications, infection.*

## INTRODUCTION

Percutaneous transhepatic cholangiography (PTC) is an established technique performed under ultrasound and fluoroscopic guidance, serving both diagnostic and therapeutic purposes in biliary obstruction (Young and Collier, 2023). Although diagnostic needs have decreased with the availability of magnetic resonance cholangiopancreatography, PTC remains a critical therapeutic option, particularly when endoscopic retrograde cholangiopancreatography (ERCP) fails or bile duct cannulation is not achievable (Coelen *et al.*, 2018).

In patients with malignant biliary obstruction undergoing palliative management, PTC and subsequent percutaneous

biliary drainage (PBD) carry substantial risks. Infectious complications — including acute cholangitis and sepsis — occur in up to 52% of cases despite antibiotic administration. Furthermore, in the context of palliative care, it is crucial to evaluate the efficacy of PTC and its influence on the quality of life of patients with malignant obstructions, particularly when their life expectancies range from 30 to 90 days.

This study aimed to evaluate the applicability and predictive accuracy of an established scoring system for complications originally developed by Makris *et al.* in 2020 in a contemporary cohort (Makris *et al.*, 2021). The primary objective was to assess the effectiveness of this scoring system in predicting mortality outcomes within this group.

## MATERIALS AND METHODS

This prospective, single-centre observational study included adult patients undergoing PTC with percutaneous biliary drainage (PBD) for malignant obstruction between October 2022 and December 2023. All PTC procedures were performed by three experienced interventional radiologists, each with more than 15 years of PTC experience and a minimum of 10 PBD procedures annually. Standardised anaesthesia protocols were used. Patients were included according to predefined criteria summarised in Table 1.

Our main objective was to identify patients at high risk of infectious complications, such as sepsis and acute cholangitis as well as 30-day mortality. Based on recently published studies, risk stratification before the procedure, which was based on the modified Karnofsky scale, albumin level, presence of ascites, haemoglobin, bilirubin, leukocytes, and international normalised ratio (INR) levels, were predictive of 30-day mortality and higher complication rates after PTC. In our scenario, we used the Eastern Cooperative Oncology Group (ECOG) Performance Status instead of the Karnofsky grading system, as the ECOG is more widely used in our region for patients with malignancy.

During the study, a standardised risk satisfaction chart was created, which divided patients into two groups, “low” and “high” risk. Patients who received 0 to 4 points were categorised as “low” risk and those who received more than 5 points were at “high” risk.

Blood tests were obtained pre-procedurally, at 48–72 hours, and at 7 days. Infectious complications were defined by standard sepsis criteria: respiratory rate  $> 22$  breaths/min, heart rate  $> 90$  beats/min, temperature  $> 38$  °C, leukocytes  $> 12 \times 10^9/l$ , or an increase of  $> 2 \times 10^9/l$  from baseline. Blood cultures were obtained selectively. The effectiveness of PTC was evaluated based on the lowering of bilirubin level after PTC by at least 25 to 50% from baseline laboratory values during 72 h after the procedure before discharge. The success rate of PTC was defined as the ability to achieve biliary access on the first attempt with a stent or biliary drain placement.

Based on local guidelines, patients should receive antibacterial prophylaxis with piperacillin/tazobactam before each biliary drainage procedure. If there is a penicillin allergy, meropenem should be prescribed. Only cases where patients received prophylaxis before both procedures, as outlined above, were defined as having received antibacterial prophylaxis. Using the national database from “Blinded for anonymity” we identified the date of death to further calculate 30 and 90-day mortality rates.

**Statistics.** The statistical analyses were conducted using the IBM SPSS Statistics v. 28 software. Fisher's Exact Test was used to compare 30-day mortality rates between patients who underwent one- and two-stage procedures. The same test was used to evaluate mortality rates and 7- and 30-day mortality rates based on risk stratification, as patients were

Table 1. Inclusion and exclusion criteria

Criteria	Description
Inclusion criteria	Age $\geq 18$ years
	Malignant biliary obstruction confirmed radiologically or clinically
	Undergoing PTC with palliative intent
	Availability of complete laboratory data (bilirubin, haemoglobin, leukocytes, albumin, INR)
	ECOG performance status documented before procedure
Exclusion criteria	Benign biliary obstruction
	Incomplete clinical or laboratory data
	Prior biliary drainage within 30 days
	Lack of follow-up mortality data
	Patients receiving PTC for diagnostic purposes only

ECOG, Eastern Cooperative Oncology Group; INR, international normalised ratio; PTC, percutaneous transhepatic cholangiography

divided into low- and high-risk groups. Effect sizes (risk ratios with 95% CIs) were calculated for all binary outcome comparisons to quantify the magnitude of observed differences. Nonparametric confidence intervals were generated due to small sample sizes.

To analyse the 90-day mortality rates between the different risk groups, the chi-square test was employed. The Fisher's Exact Test was used to determine whether risk group classification influenced the incidence of infection across patients.

A logistic regression test was used to analyse the ECOG performance status as a predictor of 30-day mortality. To further define the ECOG cut-off associated with higher mortality, ROC curve (receiver operating characteristic curve) analysis was performed, specifically by maximising Youden's index to balance sensitivity and specificity.

For multivariate analysis, a *p*-value threshold of less than 0.05 was set to indicate statistical significance.

## RESULTS

We identified 48 patients who underwent PTC for distinct reasons. From 48 patients, in 37 cases, PTC was performed for malignant obstruction and were included.

Of 48 patients who underwent PTC, 37 met the criteria for malignant biliary obstruction and were included in the study. The cohort consisted of 16 females and 21 males, with a median age of 69 years. The most common malignancy was pancreatic cancer, which accounted for 51.4% ( $n = 19$ ) of all cases. Additional information on the patient characteristics is presented in Table 2.

We adopted a scoring system previously introduced by Makris *et al.*, which included the patients' performance scale and values that in previous studies showed the most certain predictive value for the risk of complications after

Table 2. Cohort characteristics with malignant cause of biliary obstruction

Total number of patients	37
Median age in years	69 (32–86 ± 10.39)
Gender	
Male	21 (56.8%)
Female	16 (43.2%)
Causes of obstruction	
Pancreatic cancer	20 (54.1%)
Cholangiocarcinoma	12 (32.4%)
Gallbladder cancer	3 (8.1%)
Gastric cancer	2 (5.4%)
One-stage PTC procedure	11 (29.7%)
Two-stage procedure	26 (70.3%)
Median pre-procedure bilirubin level	240 µmol/l
Median post-procedure bilirubin level	132 µmol/l

PTC (Makris, *et al.*, 2021). Our modified scoring system included the ECOG scale instead of the Karnofsky scale (Table 3).

PTC was performed as a two-stage procedure in 26 patients and as a one-stage procedure in 11 patients. The success rate that was defined by achieving biliary drainage during the first attempt, was 91.9%, with failure observed in three cases. In all patients, a self-expanding uncovered metal stent was implanted. PTC was effective in lowering bilirubin levels in 28 patients by at least 25% during hospitalisation and in 15 patients by at least 50%.

Twenty-seven patients received antibiotic prophylaxis, but only 23 met all the antibacterial prophylaxis criteria. In one patient Amoxicillin/clavulanic acid was used only before the first procedure. None of the patients received prophylactic meropenem. Antibacterial prophylaxis was not administered to 13 patients.

Twenty-seven patients received antibiotic prophylaxis; however, only 23 met full criteria for correct prophylaxis administration. Infectious complications occurred in 22 patients (59.5%). Prophylaxis did not significantly influence infection rates ( $p = 0.999$ ) or short-term mortality. Additionally, patients were categorised into low- and high-risk groups to assess the impact of risk stratification on 30-day mortality rates. The analysis revealed that the risk category did not significantly influence the 30-day mortality rates. Specifically, in the low-risk group, mortality outcomes showed no significant difference (Fisher's exact test,  $p = 0.999$ ); similarly, no significant impact was noted in the high-risk group (Fisher's exact test,  $p = 0.505$ ).

The influence of risk stratification on mortality was further assessed at three different post-procedure intervals: 7, 30, and 90 days.

For 7-day mortality, one death was recorded in the high-risk group. However, statistical analysis using the Fisher's Exact

Table 3. Modified ECOG scale for prediction of outcomes after PTC procedure

	Points		
	0	1	2
Albumin (g/l)	> 35	28–35	< 28
INR	< 1.7	1.7–2.3	> 2.3
Ascites*	None	Grade 1	Grades 2 and 3
Haemoglobin (g/l)	> 110	110–100	< 100
Bilirubin (mmol/l)	< 100	100–300	> 300
Leukocytes ( $\times 10^9/l$ )	< 11	11–14	> 14
ECOG	0–1	2	3–4
Risk based on points	Low risk (0–4 points)		High risk (5+)

ECOG, Eastern Cooperative Oncology Group; PTC, percutaneous transhepatic cholangiography

Test revealed no significant impact of risk status on mortality during this interval ( $p = 0.378$ ).

Regarding 30-day mortality, three deaths were observed in the low-risk group and five in the high-risk group. Again, the Fisher's Exact Test indicated no significant difference in mortality between the two risk groups ( $p = 0.653$ ).

For the 90-day mortality, each group experienced six deaths. Similarly, the analysis performed using the chi-square test showed no significant difference in mortality rates between the groups ( $p = 0.291$ ).

Infectious complications after the procedure were identified in 22 patients (59.5%). Infection was not associated with a higher 7-day ( $p = 0.99$ ) or 30-day mortality ( $p = 0.43$ ). We found no significant difference in the infection rate between patients who received antibiotic prophylaxis and those who did not ( $p = 0.999$ ). Infection occurred in 13/23 patients (56.5%) who received adequate prophylaxis, compared with 9/14 (64.3%) who did not. The relative risk for infection with prophylaxis was 0.88 (95% CI: 0.49–1.56). The occurrence of infection among patients was also analysed according to risk stratification (low- and high-risk groups). The analysis using Fisher's exact test showed that risk group classification did not significantly influence the frequency of infections among patients ( $p = 0.491$ ).

ECOG performance status was a significant predictor of 30-day mortality. Scores of 2 or 3 were associated with higher mortality risk ( $p = 0.028$ , 95% CI: 1.14–10.41).

## DISCUSSION

In the context of malignant biliary obstruction management for patients undergoing palliation treatment, our study found no difference in the 7-day and 30-day mortality rates between the procedure types (two-stage and one-stage PTC) and risk groups. We were unable to replicate favourable outcomes from previous research when the risk stratification scale was used to further identify patients with a par-

ticularly high risk of complications and increased mortality after the procedure (Makris *et al.*, 2021). In patients who undergo palliation, it is a major concern not to negatively affect mortality rates or increase morbidity. Infectious and non-infectious complications have been well-studied in PTC patients. As observed in previous studies, PTC is associated with a high risk of infectious complications that can develop in 40–52% of patients, which can significantly impact the quality of life and potentially prolong hospital stay (Crosara *et al.*, 2013; Nennstiel *et al.*, 2015). In 2015, additional studies that compared ERCP with PTC were conducted, but were prematurely discontinued because of the high all-cause mortality in the PTC group. 30-day mortality after ERCP was 11% in comparison with 41% in the PTC group (Coelen *et al.*, 2018).

The patients included in our study did not receive further treatments such as chemotherapy. This study shows that risk stratification should be performed on an individual basis and that scales should not be used to make treatment decisions (Makris *et al.*, 2021). Hypothetically, considering the mortality and median survival rates in this patient group, we suggest that PTC with biliary drainage should be reserved and performed in patients with severe symptoms caused by cholestasis, including pruritus or discolouration owing to soluble vitamin deficits, such as vitamin K, or those who would further undergo palliative chemotherapy.

In 2020, James Rees *et al.* published a large retrospective cohort study that included 16,822 patients who underwent palliative PTC between 2001 and 2014 (Keulen *et al.*, 2022). The authors reported a 7-day mortality of 5.2% and a 30-day mortality of 23.1%, with a median survival of 92 days (Nikolić *et al.*, 2022). A smaller study of 186 patients, which was published by Keulen *et al.*, showed a lower mortality rate, with 30-day mortality of 11% (Duzkopru *et al.*, 2024). Another study that was conducted in the Netherlands reported 30-day mortality of 17.2% (Nennstiel *et al.*, 2015). In contrast, our results were average in terms of 30-day mortality and reached 16.2%.

The ECOG score has been shown to predict complications and increased post-procedural mortality. In previous studies, ECOG cutoff values  $\geq 2$  were used, showing more favourable results in those with a performance status between 0 and 1 (Tapping *et al.*, 2011; Nikolić, *et al.*, 2022). Similarly, we also found that the ECOG scale has a good predictive value, which can help define patients who would probably not benefit from PTC and in whom it should be avoided.

Recognising that patients undergoing PTC for palliation often have high mortality and complication rates, our primary goal was to identify those at particularly high risk. To achieve this, we adopted the scoring system introduced by Makris *et al.* (2021). This system incorporates patient performance scales and values that previous studies have shown to be reliable predictors of complication risks after PTC (Walter *et al.*, 2013; Giurazza *et al.*, 2019). The authors showed good results in predicting the 30-day mortality and complication rates after the procedure using a novel

grading scale. Our modified scoring system included the ECOG scale instead of the Karnofsky scale. Unfortunately, we failed to achieve the desired results using the “modified Karnofsky scale” proposed by the authors. The outcomes may have been affected by the small sample size, and further research involving a larger cohort is required.

This is the only prospective study that has evaluated procedural success and mortality rates seven, 30, and 90 days after PTC in the last decade. In a previous study, the biliary access rate on the first attempt varied from 63–86% (Tapping *et al.*, 2011). In 2019, a higher success rate was reported in published research, where authors achieved 100% biliary access with clinical success, which was defined as a bilirubin reduction of 95.7% after the procedure. It should be noted that the study cohort size was small, but this was a multi-centre study (Turan *et al.*, 2022). A high success rate of 98% in PTC was also reported by Walter *et al.* in a small cohort of 42 patients (Walter *et al.*, 2013). We demonstrated a high technical success rate of 91.9%, highlighting the technical challenges associated with malignant obstructions and patient frailty. Several larger single-centre studies also highlight the importance of operator expertise. High technical success and lower complication rates were consistently achieved when PTC was performed by experienced interventional radiologists. One 12-year retrospective analysis of nearly 600 patients showed that excellent outcomes were largely attributable to the procedures being carried out in a high-volume, highly experienced centre, leading the authors to recommend that PTC be concentrated in such settings (Kokas *et al.*, 2021). In most studies, patients who underwent PTC subsequently received surgery, chemotherapy, or a combination of both. This finding suggests that these patients had a localised disease, which may present fewer challenges to biliary drainage.

Key limitations include the small sample size, single-centre design, and observational nature of the study. Potential biases in infection reporting and lack of standardised follow-up protocols must also be considered. Larger multi-centre studies are needed to validate these findings. In conclusion, infectious complications after percutaneous biliary drainage are common in our hospital and occur in 59.5% of cases. Our data showed that antibiotic prophylaxis did not affect short-term mortality in patients with malignant biliary obstruction. We recommend individualised pre-PTC drainage procedure risk stratification in patients with oncological disease who receive palliative symptomatic therapy and for whom further surgery or chemotherapy is not applicable.

## ETHICS

This study was approved by the Ethics Committee of Pauls Stradiņš Clinical University Hospital, of the “Blinded for anonymity”. All procedures involving human participants performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later

amendments or comparable ethical standards. The requirement for informed consent was waived.

## CONFLICT OF INTEREST

The authors declare no conflict of interest.

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## RISKA IZVĒRTĒŠANA PIRMS PROCEDŪRAS UN ĀRSTĒŠANAS REZULTĀTI PĒC PERKUTĀNAS TRANSHEPĀTISKAS ŽULTSVADU DRENĀŽAS PACIENTIEM AR MALIGNU OBSTRUKCIJU: PROSPEKTĪVS VIENA CENTRA PĒTĪJUMS

Pētījumos ir noteikti vairāki augstas mirstības un saslimstības riska faktori. Ir izveidotas vairākas riska izvērtēšanas skalas, kuras pierādījušas savu efektivitāti augsta riska pacientu identificēšanā. Joprojām trūkst pētījumu, kuri izvērtētu riskus pacientiem, kad perkutāna biliāra drenāža (PTH) tiek veikta ar paliatīvu mērķi. Šo pacientu dzīves ilgums ir īss, un pamata mērķis ir dzīves kvalitātes saglabāšana. Šis bija novērojumu pētījums ar mērķi atkārtot iepriekš publicētus rezultātus, pielietojot riska izvērtēšanas skalu klīniskā praksē un identificējot papildu riska faktorus. Pētījuma laikā netika veikta iekļaušanās ārstēšanas procesā, lēmumu pieņemšanā vai sniegtas rekomendācijas. Pamatojoties uz pacientu riska grupu, tika veikta tālāka statistiskā analīze, lai izvērtētu saistību ar 7, 30 un 90 dienu mirstību. Dati par nāvi tika iegūti no Latvijas Republikas Pilsonības un migrācijas lietu pārvaldes datu bāzes. Pētījumā tika iekļauti 37 pacienti. Pacienti tika izvērtēti pirms procedūras, nosakot viņiem Austrumu Kooperatīvās Onkoloģijas grupas (ECOG) indeksu un aizpildot riska skalu. Nacionālā datu bāze tika izmantota, lai identificētu pacientus, kuriem nāve iestājās 7, 30 vai 90 dienas pēc procedūras. Šajā pētījumā mēs nespējām atkārtot labvēlīgos rezultātus, kas tika publicēti iepriekš, izmantojot “modificēto ECOG skalu”, tomēr apstiprinājām, ka ECOG skala ir neatkarīgs riska faktors, kas uzticami identificē pacientus ar augstu mirstības risku ( $p = 0,028$ ). Infekcijas komplikācijas ir bieži sastopamas pēc perkutānas žults drenāžas. Antibiotiku profilakse neietekmē istermiņa mirstību. Pacienti ar onkoloģiskām slimībām, kuriem paliatīvos nolūkos tiek veikta perkutāna žults drenāža, pirms procedūras ieteicams individuāli izvērtēt riskus.