CLINICAL PREDICTORS OF MALIGNANT ETIOLOGY IN PATIENTS PRESENTING WITH OBSTRUCTIVE JAUNDICE: A CROSS-SECTIONAL STUDY

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ABSTRACT

Background: Malignant and benign biliary obstruction can present with similar cholestatic symptoms. Clinical features available at first contact may help prioritize patients for expedited tissue diagnosis and biliary decompression, but their discriminatory value varies across referral settings.

Methods: This post hoc secondary analysis included 100 adults with obstructive jaundice enrolled in a tertiary-care cross-sectional study. Final etiology was established by tissue acquisition and/or operative findings. The primary outcome was malignant obstruction. Age, sex, pruritus, right upper quadrant mass, abdominal pain, anorexia, and fever were evaluated using Welch's t test, Fisher's exact test, odds ratios, phi coefficients, and Firth bias-reduced logistic regression. Discrimination was assessed using receiver operating characteristic analysis and bootstrap optimism correction.

Results: Malignant obstruction was present in 76 patients and benign obstruction in 24. Patients with malignancy were older than those with benign disease (61.70 ± 9.33 vs 38.83 ± 11.24 years; $t=9.03$; $p<0.001$; Cohen $d=2.33$). Pruritus and a right upper quadrant mass were positively associated with malignancy, whereas abdominal pain and fever were negatively associated. The univariable Firth odds ratio for malignancy was 9.90 per 10-year increase in age, 16.21 for pruritus, and 67.09 for a right upper quadrant mass. An age cutoff of ≥48 years had 94.7% sensitivity and 83.3% specificity. An exploratory five-variable Firth model had an apparent area under the receiver operating characteristic curve of 0.958 and an optimism-corrected value of 0.944, although individual adjusted estimates were imprecise.

Conclusions: Older age, pruritus, and a palpable right upper quadrant mass were strong univariable markers of malignant biliary obstruction, while abdominal pain and fever favored benign disease. The apparent performance of an exploratory clinical model was high, but sparse cells, referral bias, and absence of external validation preclude use as a stand-alone decision rule.

Keywords: Biliary Obstruction, Cholestasis, Clinical Prediction, Malignant Biliary Stricture, Obstructive Jaundice, Pruritus.

INTRODUCTION

Obstructive jaundice results from impaired bile flow and may arise from malignant tumors, common bile duct stones, postoperative strictures, congenital abnormalities, or inflammatory disease.

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The immediate clinical priorities are to establish the presence and level of obstruction, differentiate malignant from benign etiologies, identify cholangitis or organ dysfunction, and plan appropriate tissue acquisition and drainage [1]. Delayed recognition of malignancy can postpone staging and potentially curative treatment, whereas unnecessary invasive investigation in benign disease exposes patients to avoidable procedure-related risk. Modern diagnostic pathways integrate transabdominal ultrasonography, cross-sectional imaging, magnetic resonance cholangiopancreatography, endoscopic ultrasound, and endoscopic retrograde cholangiopancreatography-based tissue acquisition. Current European Society of Gastrointestinal Endoscopy and American Society for Gastrointestinal Endoscopy guidance emphasizes careful review of cross-sectional imaging and selective use of endoscopic ultrasound, endoscopic retrograde cholangiopancreatography sampling, and cholangioscopy according to stricture location and pretest probability [2,3]. Endoscopic retrograde cholangiopancreatography is increasingly reserved for therapeutic intervention and targeted tissue sampling rather than used as a purely diagnostic procedure [3,4].

Before advanced imaging is performed, the bedside phenotype may already modify the probability of malignancy. Older age, painless jaundice, weight loss, pruritus, palpable gallbladder or right upper quadrant mass, high bilirubin, and cholestatic enzymes have been incorporated into previous prediction models [5,6]. Conversely, fever and painful jaundice may suggest choledocholithiasis or acute cholangitis, although malignant obstruction can also become infected. The predictive value of these findings depends on disease prevalence, referral pattern, and the mix of proximal and distal obstruction.

Tertiary gastroenterology cohorts in low- and middle-income settings often contain a high proportion of advanced malignant obstruction and may differ substantially from community populations [7,8]. Clinical prediction estimates generated in such cohorts require careful handling because complete or near-complete separation is common; for example, a particular symptom may occur exclusively in one outcome group. Conventional logistic regression can then yield infinite or severely biased estimates. Firth bias-reduced logistic regression provides finite, more stable estimates in separated datasets [9,10].

The parent study prospectively compared ultrasonography, magnetic resonance cholangiopancreatography, endoscopic ultrasound, and endoscopic retrograde cholangiopancreatography in 100 patients with obstructive jaundice. The present secondary analysis addresses a distinct question: whether clinical characteristics recorded before definitive etiologic adjudication can identify patients with malignant obstruction. We evaluated age, sex, pruritus, a palpable right upper quadrant mass, abdominal pain, anorexia, and fever and developed an exploratory multivariable clinical model. We hypothesized that older age, pruritus, and a right upper quadrant mass would favor malignancy, whereas pain and fever would favor benign obstruction.

MATERIALS AND METHODS

Study Design and Setting

This was a post hoc secondary analysis of a single-center cross-sectional analytical study conducted in the Department of Medical Gastroenterology, Gandhi Medical College and Gandhi Hospital, Secunderabad, Telangana, India. The parent study enrolled 100 patients over 18 months after institutional ethics approval. Reporting was structured in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology statement [11].

Participants

Patients presenting with a clinical and biochemical pattern of obstructive jaundice were screened. The dissertation protocol stated an eligible age range of 18-70 years. Exclusion criteria were a hepatocellular pattern of jaundice, a previously established cause of obstruction, inability to undergo endoscopic ultrasound or endoscopic retrograde cholangiopancreatography, and refusal of required investigations.

Clinical Variables

The prespecified clinical variables available in the participant-level master chart were age, sex, jaundice, pruritus, palpable right upper quadrant mass, abdominal pain, anorexia, and fever. Jaundice was present in all participants and was therefore not modeled. Weight loss and quantitative biochemical variables appeared in the case proforma but were not retained in the analyzable master chart and were not reconstructed or imputed.

Diagnostic Procedures and Equipment

All participants underwent transabdominal ultrasonography (USG), magnetic resonance cholangiopancreatography (MRCP), endoscopic ultrasound (EUS), and endoscopic retrograde cholangiopancreatography (ERCP) within approximately 10 days. Ultrasonography was performed after at least four hours of fasting using a GAIAMT 8800 Medison real-time scanner with color Doppler, a 3.5-MHz transducer, and a 5-MHz curvilinear probe. The biliary tree was assessed in transverse, oblique, and sagittal planes for ductal dilatation, level and suspected cause of obstruction, masses, lymphadenopathy, portal vein thrombosis, cholelithiasis, and focal liver lesions.

Magnetic Resonance Cholangiopancreatography

Magnetic resonance cholangiopancreatography was performed using a 1.5-T Signa system (GE Medical Systems, Milwaukee, Wisconsin, United States) with a body coil. The protocol included an axial localizer, axial T2-weighted fast spin-echo imaging, and single-shot fast spin-echo cholangiographic acquisitions in coronal and oblique planes. Images were evaluated on an Advantage Windows workstation (GE Medical Systems).

Endoscopic Ultrasound and Endoscopic Retrograde Cholangiopancreatography

Endoscopic ultrasound was performed under conscious sedation using an Olympus EUM-20 echoendoscope (Olympus Corporation, Tokyo, Japan). The extrahepatic biliary tract was examined from the papilla toward the hepatic hilum by an experienced endosonographer with a trainee. Endoscopic retrograde cholangiopancreatography was performed by an experienced biliary endoscopist with a trainee using a conventional Olympus side-viewing duodenoscope. Operators were reported to interpret endoscopic retrograde cholangiopancreatography without knowledge of endoscopic ultrasound and magnetic resonance cholangiopancreatography results.

Outcome Adjudication

The primary outcome was malignant biliary obstruction. Cholangiocarcinoma (CCA), carcinoma of the pancreatic head (Ca HoP, gallbladder carcinoma (Ca GB), and ampullary carcinoma were classified as malignant. Choledocholithiasis, postoperative biliary stricture, and choledochal cyst were classified as benign. Final etiology was established using ultrasound-guided fine-needle aspiration cytology, endoscopic retrograde cholangiopancreatography-based biopsy or cytology, and/or operative findings. No indeterminate final diagnoses remained.

Statistical Analysis

Continuous variables were summarized as mean ± standard deviation and categorical variables as number and percentage. Age was compared using Welch’s independent-samples t test because group variances and sizes differed; Cohen d quantified the standardized mean difference. Categorical variables were compared using two-sided Fisher’s exact tests because several cells were sparse or zero. Odds ratios with 95% confidence intervals and Pearson chi-square statistics with phi coefficients were additionally reported as measures of association. For zero cells, continuity-corrected odds ratios were used for descriptive 2 × 2 estimates.

Statistical Modeling

Firth bias-reduced logistic regression was used for univariable and multivariable modeling because right upper quadrant mass and fever produced complete separation [9,10]. Age was expressed per 10-year increase. The prespecified exploratory multivariable model included age, pruritus, right upper quadrant mass, abdominal pain, and fever; sex and anorexia were omitted to limit overfitting and because they showed little univariable evidence of association. Model discrimination was summarized by the area under the receiver operating characteristic curve, and the Brier score assessed overall probabilistic error. Bootstrap resampling was used to estimate optimism in the area under the curve. An exploratory age cutoff was selected by the maximum Youden index, with sensitivity, specificity, positive predictive value, and negative predictive value reported with Wilson 95% confidence intervals. The cutoff and model were derived in the same cohort and were not externally validated. Analyses were performed using Python version 3.13.5, pandas version 2.2.3, SciPy version 1.17.0, scikit-learn version 1.8.0, and custom implementation of the Firth adjusted-score algorithm. Two-sided $p<0.05$ was considered statistically significant.

Ethical Considerations

The parent study was approved by the Institutional Ethics Committee of Gandhi Medical College. Written informed consent was obtained from all participants. This secondary analysis used de-identified participant-level data.

RESULTS

All 100 participants were included. Malignant biliary obstruction was confirmed in 76 patients and benign obstruction in 24. Mean age was 56.21 ± 13.84 years, and 61 participants were women. Jaundice was universal; pruritus occurred in 71%, a palpable right upper quadrant mass in 44%, abdominal pain in 42%, anorexia in 61%, and fever in 16%. Baseline clinical characteristics are presented in Table 1.

Table 1. Baseline demographic and clinical characteristics of the study cohort

Characteristic	Overall cohort (n=100)
Age, years	56.21 ± 13.84
Women	61 (61.0%)
Men	39 (39.0%)
Jaundice	100 (100.0%)
Pruritus	71 (71.0%)
Palpable right upper quadrant mass	44 (44.0%)
Abdominal pain	42 (42.0%)

Characteristic	Overall cohort (n=100)
Anorexia	61 (61.0%)
Fever	16 (16.0%)
Malignant obstruction	76 (76.0%)
Benign obstruction	24 (24.0%)

Values are mean ± standard deviation or number (percentage). Jaundice was present in every participant and was not entered into predictor models.

Cholangiocarcinoma was the most frequent final diagnosis, followed by carcinoma of the pancreatic head and gallbladder carcinoma. Choledocholithiasis accounted for two-thirds of benign obstruction. The complete etiologic spectrum is shown in Table 2.

Table 2. Final etiologies of obstructive jaundice

Final etiology	Number	Percentage of cohort	Etiologic category
Cholangiocarcinoma	29	29.0%	Malignant
Carcinoma of the pancreatic head	22	22.0%	Malignant
Gallbladder carcinoma	17	17.0%	Malignant
Ampullary carcinoma	8	8.0%	Malignant
Choledocholithiasis	16	16.0%	Benign
Postoperative biliary stricture	4	4.0%	Benign
Choledochal cyst	4	4.0%	Benign
Total	100	100.0%	All etiologies

Final etiology was established by fine-needle aspiration cytology, endoscopic retrograde cholangiopancreatography-based biopsy or cytology, and/or operative findings. There were no indeterminate final etiologies.

Patients with malignant obstruction were substantially older than patients with benign obstruction (61.70 ± 9.33 vs 38.83 ± 11.24 years; Welch t=9.03; $p<0.001$; Cohen d=2.33). Pruritus and a palpable right upper quadrant mass were strongly associated with malignancy. Abdominal pain and fever were inversely associated, and every participant with fever had a benign final etiology. Sex and anorexia were not significantly associated. The complete group comparisons, test statistics, and effect sizes are presented in Table 3.

Table 3. Clinical characteristics according to malignant or benign biliary obstruction

Variable	Malignant obstruction (n=76)	Benign obstruction (n=24)	Effect estimate (95% confidence interval)	Statistical test	Effect size
Age, years	61.70 ± 9.33	38.83 ± 11.24	Mean difference 22.86 years	Welch t=9.03; $p<0.001$	Cohen d=2.33
Male sex	30 (39.5%)	9 (37.5%)	Odds ratio 1.09 (0.42-2.80)	Fisher p=1.000; χ^2=0.03	Phi=0.017
Pruritus	65 (85.5%)	6 (25.0%)	Odds ratio 17.73 (5.76-54.52)	Fisher $p<0.001$; χ^2=32.45	Phi=0.570
Palpable right upper quadrant mass	44 (57.9%)	0 (0.0%)	Corrected odds ratio 67.09 (3.93-1144.08)	Fisher $p<0.001$; χ^2=24.81	Phi=0.498

Variable	Malignant obstruction (n=76)	Benign obstruction (n=24)	Effect estimate (95% confidence interval)	Statistical test	Effect size
Abdominal pain	23 (30.3%)	19 (79.2%)	Odds ratio 0.11 (0.04-0.34)	Fisher p<0.001; χ^2=17.91	Phi=0.423
Anorexia	43 (56.6%)	18 (75.0%)	Odds ratio 0.43 (0.16-1.22)	Fisher p=0.150; χ^2=2.60	Phi=0.161
Fever	0 (0.0%)	16 (66.7%)	Corrected odds ratio 0.003 (0.0002-0.061)	Fisher p<0.001; χ^2=60.32	Phi=0.777

Values are mean ± standard deviation or number (percentage). Categorical p values are from two-sided Fisher's exact tests; Pearson chi-square statistics are shown as test statistics. Phi is the effect-size measure for 2 × 2 associations. Corrected odds ratios use a 0.5 continuity correction because one cell was zero.

In univariable Firth regression, each 10-year increase in age was associated with nearly tenfold greater odds of malignant obstruction. Pruritus and a right upper quadrant mass were also strong positive markers, whereas abdominal pain and fever were negative markers. In the multivariable model, individual associations attenuated markedly and confidence intervals widened because clinical findings were highly correlated and several cells showed complete separation. Age retained borderline evidence of an independent association, and fever retained borderline inverse evidence. The regression estimates are presented in Table 4.

Table 4. Firth bias-reduced logistic regression for malignant biliary obstruction

Variable	Univariable Firth odds ratio (95% confidence interval)	Univariable p value	Adjusted Firth odds ratio (95% confidence interval)	Adjusted p value
Age, per 10-year increase	9.90 (3.70-26.50)	<0.001	3.48 (0.91-13.33)	0.069
Male sex	1.07 (0.42-2.73)	0.887	Not included	Not applicable
Pruritus	16.21 (5.37-48.90)	<0.001	1.00 (0.13-7.46)	1.000
Palpable right upper quadrant mass	67.09 (3.81-1181.07)	0.004	4.31 (0.10-187.66)	0.448
Abdominal pain	0.12 (0.04-0.36)	<0.001	1.12 (0.13-9.65)	0.917
Anorexia	0.46 (0.17-1.26)	0.129	Not included	Not applicable
Fever	0.00 (0.00-0.07)	<0.001	0.03 (0.00-1.00)	0.050

Adjusted estimates are from a prespecified exploratory model containing age, pruritus, palpable right upper quadrant mass, abdominal pain, and fever. Male sex and anorexia were not included to limit overfitting. Confidence intervals are 95% confidence intervals.

Age alone had an area under the receiver operating characteristic curve of 0.944. A data-derived threshold of age ≥48 years yielded 94.7% sensitivity and 83.3% specificity. The five-variable exploratory Firth model had an apparent area under the curve of 0.958, a Brier score of 0.048, and an optimism-corrected area under the curve of 0.944. Performance estimates are summarized in Table 5 and illustrated in Figure 1.

Table 5. Discrimination and exploratory operating characteristics

Metric	Age alone	Exploratory multivariable clinical model
Area under receiver operating characteristic curve	0.944	0.958 apparent; 0.944 optimism-corrected

Metric	Age alone	Exploratory multivariable clinical model
Bootstrap 95% interval for area under the curve	0.886-0.986	0.928-0.997
Brier score	Not calculated	0.048
Data-derived cutoff	Age ≥48 years	No probability cutoff proposed
Sensitivity at stated cutoff	94.7% (87.2%-97.9%)	Not applicable
Specificity at stated cutoff	83.3% (64.1%-93.3%)	Not applicable
Positive predictive value	94.7% (87.2%-97.9%)	Not applicable
Negative predictive value	83.3% (64.1%-93.3%)	Not applicable

The age cutoff was selected by the maximum Youden index in the same cohort. Confidence intervals for sensitivity, specificity, and predictive values are Wilson 95% confidence intervals. The multivariable model was internally assessed with bootstrap optimism correction but was not externally validated.

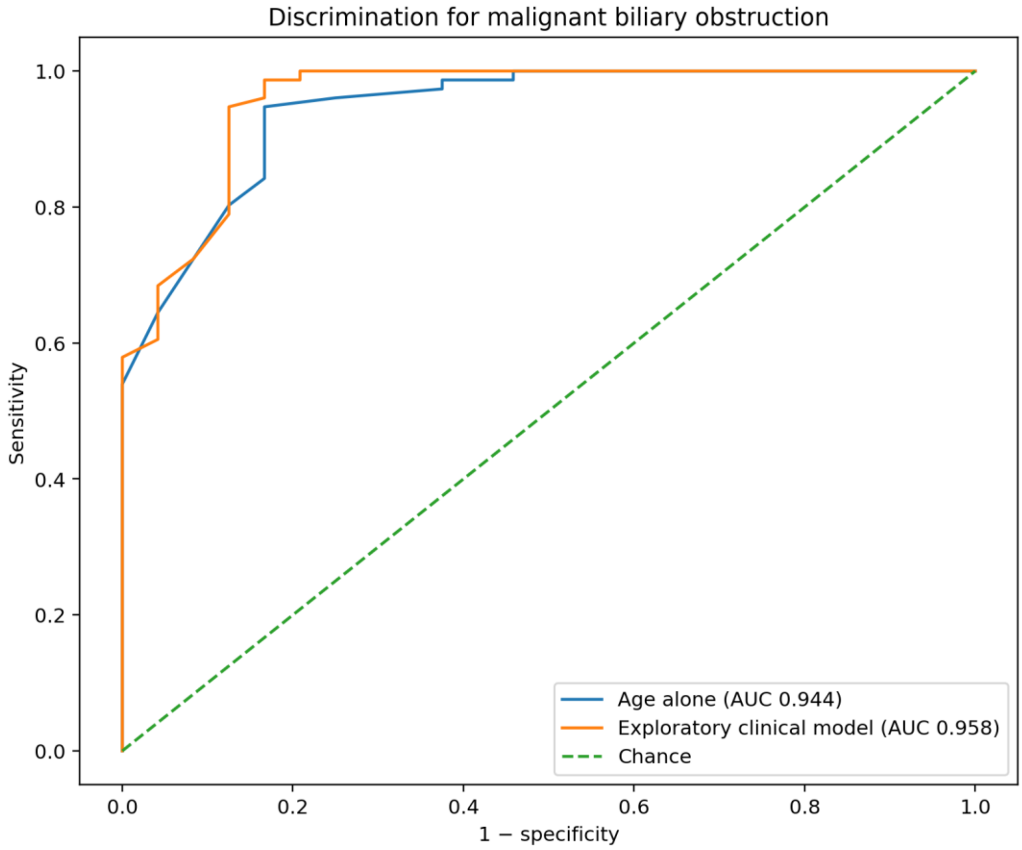

Figure 1. Receiver operating characteristic curves for age alone and the exploratory five-variable clinical model. AUC, area under the receiver operating characteristic curve.

DISCUSSION

This secondary analysis identified a clinically recognizable phenotype associated with malignant biliary obstruction in a tertiary referral cohort. Older age, pruritus, and a palpable right upper quadrant mass were strong positive univariable markers, whereas abdominal pain and fever favored benign disease. Age alone showed excellent apparent discrimination. A multivariable model combining five bedside variables also showed high apparent and bootstrap-corrected discrimination, but individual adjusted odds ratios were unstable because symptoms clustered strongly by etiology and the dataset contained complete separation.

The association with age was the most consistent finding. Malignant biliary obstruction commonly results from cholangiocarcinoma, pancreatic cancer, gallbladder cancer, and ampullary cancer, all of which become more prevalent with advancing age. In the present cohort, the mean age difference exceeded 22 years and the standardized effect was very large. Previous malignancy-prediction studies have also incorporated age as a core variable [5,6]. Nevertheless, the threshold of 48 years was selected in the same dataset and should not be interpreted as a universal clinical boundary.

Pruritus was strongly associated with malignancy. Persistent or slowly progressive obstruction permits accumulation of bile acids and pruritogens, whereas abrupt stone-related obstruction may present earlier with pain or infection. However, pruritus is not cancer-specific and occurs in benign cholestatic disorders. Its value lies in modifying probability when interpreted with age, symptom tempo, biochemical findings, and imaging rather than functioning as an isolated diagnostic criterion.

A palpable right upper quadrant mass occurred only among patients with malignant disease. This finding may reflect a distended gallbladder or a locally advanced gallbladder, pancreatic, or hilar mass. The corrected odds ratio was correspondingly large but imprecise, with a very wide confidence interval. Complete separation makes the direction of association credible within this cohort but prevents precise estimation of its magnitude. It also suggests that some patients presented with relatively advanced disease, limiting generalizability to earlier-stage cancer.

Abdominal pain and fever favored benign obstruction. Choledocholithiasis and postoperative strictures can cause acute pressure changes, bacterial contamination, and cholangitis, whereas malignant obstruction is often initially painless. All 16 febrile participants in the dataset had benign disease. This pattern should not be used to exclude malignancy: malignant strictures can develop cholangitis, especially after instrumentation or incomplete drainage. Current diagnostic guidance therefore integrates clinical assessment with imaging and tissue acquisition rather than relying on symptom patterns alone [2,3].

The high prevalence of malignancy, 76%, materially influences the apparent predictive values. It reflects the tertiary-care setting and the study requirement that participants undergo ultrasonography, magnetic resonance cholangiopancreatography, endoscopic ultrasound, and endoscopic retrograde cholangiopancreatography. Similar studies from referral hospitals have reported substantial malignant burdens, although the etiologic mix varies geographically [7,8]. Positive and negative predictive values from this cohort should not be transferred to community populations with a lower prevalence of cancer.

The attenuation of all symptom effects in the multivariable Firth model deserves emphasis. Age, pruritus, mass, pain, and fever were not independent orthogonal variables; rather, they described overlapping clinical syndromes. The sample also contained only 24 benign outcomes, and two predictors generated zero cells. Firth regression appropriately produced finite estimates [9,10], but it cannot create information absent from sparse data. The model should therefore be considered exploratory and not a validated clinical score.

Clinically, these findings may support triage rather than diagnosis. An older patient with progressive jaundice, pruritus, little pain, and a palpable right upper quadrant mass should undergo prompt high-quality cross-sectional imaging and expedited endoscopic or percutaneous tissue acquisition according to stricture location and local expertise [2,3]. Conversely, pain and fever require urgent assessment for cholangitis and biliary decompression, even when a benign cause is suspected. Neither phenotype should delay definitive evaluation.

Limitations

1. It was a post hoc analysis of a single-center tertiary-care cohort enriched for malignancy, producing referral, work-up, and spectrum bias. The findings require external validation before clinical use.
2. The parent dissertation was designed to compare imaging modalities rather than to develop a clinical prediction model.[5].
3. Complete separation occurred for right upper quadrant mass and fever, and only 24 benign outcomes were available. Although Firth regression reduced small-sample bias and yielded finite estimates, adjusted confidence intervals remained very wide and the model was vulnerable to overfitting.
4. The receiver operating characteristic cutoff and multivariable model were developed and assessed in the same cohort. Bootstrap optimism correction was performed, but this does not substitute for temporal or geographic external validation.

CONCLUSIONS

In this tertiary-care cohort of obstructive jaundice, older age, pruritus, and a palpable right upper quadrant mass were strong univariable clinical markers of malignant obstruction, while abdominal pain and fever favored benign disease. Age alone and an exploratory five-variable model showed high apparent discrimination, but sparse data, complete separation, and referral enrichment substantially limit transportability. Clinical features may help prioritize diagnostic pathways, but malignancy must be confirmed through guideline-directed imaging and tissue acquisition.

Declarations

Ethics approval and consent to participate: Approved by the Institutional Ethics Committee of Gandhi Medical College. Written informed consent was obtained from all participants.

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