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Patient-Reported Quality of Life and Comfort Following Endoscopic Pancreatic Duct Stent Placement in Acute Pancreatitis: A Single-Center Exploratory Study

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Abstract

Background: Although endoscopic pancreatic duct stent placement is not currently recommended as a routine treatment in clinical guidelines for acute pancreatitis (AP), our institution has accumulated extensive clinical experience with this procedure,

having treated over 2,000 patients to date. While previous clinical practice and studies by our team have established the efficacy and safety of this intervention, its impact on patient-reported outcomes (PROs) remains largely uncharacterized. To further establish a comprehensive evidence chain for this practice from multidimensional perspectives, this study aimed to describe the characteristics of PROs in patients with AP receiving pancreatic duct stents during their recovery, thereby evaluating its influence on patients' subjective rehabilitation.

Methods: We conducted a single-center, longitudinal observational study of 146 patients with AP who underwent endoscopic pancreatic duct stent placement between October 2025 and April 2026. The clinical decision for stenting was individualized, based on the presence of prominent abdominal pain/distension, marked peripancreatic fluid exudation on contrast-enhanced CT, and significant elevation of inflammatory markers. All procedures were performed by a single senior endoscopist. PROs were assessed using the adapted Pancreatitis Quality of Life Instrument (PANQOLI) and the General Comfort Questionnaire (GCQ) at admission, before discharge, and 2 weeks post-discharge.

Results: Among the 146 patients (biliary AP: 42.5%; hypertriglyceridemic AP: 38.4%), no procedure-related adverse events (e.g., bleeding, perforation, or exacerbation of pancreatitis) were observed. Mean PANQOLI total scores increased from 19.84 ± 3.92 at admission to 68.04 ± 2.93 before discharge, and 82.23 ± 2.35 at 2 weeks post-discharge. Similarly, mean GCQ scores improved significantly from 57.82 ± 3.35 to 93.51 ± 3.31 and 103.55 ± 2.42, respectively ($P<0.001$ for time effects). Notably, changes in objective laboratory inflammatory markers showed weak correlations with the trajectory of these subjective PRO scores.

Conclusion: In this cohort study, patients with AP who underwent pancreatic duct stent placement demonstrated significant short-term improvements in quality of life and comfort, with no procedure-related adverse events observed. The divergence between subjective improvement and objective inflammatory markers highlights the value of incorporating patient-reported outcomes (PROs) into efficacy assessment frameworks. These exploratory findings provide a supplementary dimension of

evidence for this off-guideline practice; however, further confirmation through future controlled studies is warranted.

Keywords: Acute pancreatitis, Pancreatic duct stent placement, Patient-reported outcomes, Quality of life, Comfort, Symptoms

Introduction

Acute pancreatitis (AP) is a common acute abdominal condition of the digestive system, characterized by a complex pathogenesis and marked clinical heterogeneity; in severe cases, it may progress to multiple organ failure[1]. The global incidence of AP has risen steadily, imposing an increasingly heavy disease burden [2-3]. Current management remains predominantly conservative, relying on fluid resuscitation and organ support [4-5], while direct etiology-targeted interventions are still lacking. Accumulating evidence suggests that pancreatic duct hypertension and the ensuing systemic inflammatory cascade are central to disease progression, and that timely relief of ductal hypertension—thereby interrupting the vicious inflammatory cycle—may be critical to improving outcomes [6-7].

Building on the pathophysiological role of pancreatic duct hypertension in AP progression, our team has focused on endoscopic pancreatic duct stent placement via ERCP [8-9]. Over the past decade, we have accumulated substantial clinical experience with this intervention[10-13]. In a retrospective case series of 336 patients, we previously demonstrated that early pancreatic stenting (within 48 hours of admission) achieved a 98.2% technical success rate, significantly shortening the time to oral refeeding and length of hospital stay, with a procedure-related adverse event rate of only 0.3% [14]. Furthermore, a subsequent retrospective cohort study comparing stenting with standard conservative treatment indicated that early stenting was associated with reduced time to pain relief, earlier oral refeeding, and a lower incidence of new-onset organ failure [15]. These findings have since been corroborated by several independent groups [16-17], highlighting the potential clinical value of this approach despite its current off-guideline status.

To date, however, evidence for these therapeutic effects has relied predominantly on objective indicators—such as serum amylase, lipase, C-reactive protein (CRP), and imaging findings. While objective measures can delineate the biological trajectory of the disease, they often fail to capture the patient's lived experience. Furthermore, the improvement in objective parameters does not always parallel the improvement in subjective perception [18-19] Patient-reported outcomes (PROs)—subjective outcome measures obtained through direct patient self-report — represent an essential complement to traditional objective outcomes [20-24]. Our previous qualitative work revealed that AP patients carry a substantial burden of negative psychological states and disease-related symptoms during their illness [25]. However, whether patients derive concurrent benefit in symptom relief, gastrointestinal recovery, and emotional status following pancreatic duct stent placement remains largely unexplored from a PRO perspective.

Despite the clinical use of this intervention, endoscopic pancreatic duct stenting is not currently incorporated as a routine recommendation in AP management guidelines. To supplement the existing clinical evidence chain for this off-guideline practice with patient-centered data, we conducted a longitudinal observational study. This investigation specifically aimed to characterize the dynamic changes in PROs—encompassing quality of life, comfort, and symptom-related emotional status—alongside objective inflammatory indicators in patients receiving pancreatic duct stents. By exploring the correlation between these subjective trajectories and objective biomarker changes, this study seeks to provide patient-derived evidence to inform future clinical decision-making and optimize multimodal AP care.

Methods and materials

1. Study Participants

This single-center, longitudinal observational study used convenience sampling to recruit patients with AP treated at the Department of Hepatobiliary Surgery, General Hospital of Ningxia Medical University, from October 2025 through April

2026. **Inclusion criteria were as follows**: (1) fulfillment of the diagnostic criteria for acute pancreatitis [1], defined as the presence of at least two of the following three features: ① acute onset of persistent upper abdominal pain; ② serum amylase and/or lipase activity elevated to at least three times the upper limit of normal; and ③ characteristic imaging findings of acute pancreatitis on contrast-enhanced CT, MRI, or abdominal ultrasound; (2) having undergone ERCP with pancreatic duct stent placement; and (3) provision of informed consent. **Exclusion criteria were:** (1) acute exacerbation of chronic pancreatitis; (2) pancreatitis secondary to pancreatic cancer or other malignancies; (3) severe cognitive impairment or psychiatric disorder precluding cooperation with follow-up; and (4) substantial missing data precluding meaningful analysis.

To ensure data quality, individual questionnaires were excluded if they met any of the following criteria: (1) a missing-item rate >10%; (2) an evident response pattern (e.g., consecutive identical answers) or internal logical inconsistency; or (3) loss to follow-up for reasons unrelated to the study (e.g., accidental death, transfer to another medical facility).

2. Endoscopic Intervention and Procedural Rationale

The clinical criteria for selecting patients for pancreatic duct stent placement were as follows: (1) the presence of prominent abdominal pain and/or distension; and (2) characteristic imaging findings on contrast-enhanced abdominal CT, including marked peripancreatic fluid exudation, accumulation, and necrotic debris collection.

Surgical Technique and Operator Expertise: The endoscopic procedure was performed following a standardized protocol derived from our previous clinical practice [14]. Under fluoroscopic guidance, a guidewire was gently inserted into the pancreatic duct. After confirming the intrapancreatic position, a plastic pancreatic duct stent (COOK Medical, Bloomington, IN, USA; 5Fr diameter, 15 cm length) was deployed. As illustrated in Figure 1, the stent was deployed under direct endoscopic and fluoroscopic guidance. The left panel demonstrates the endoscopic view of the stent emerging from the major duodenal papilla into the duodenal lumen (blue

arrowhead). The right panel shows the corresponding fluoroscopic image, confirming the appropriate positioning and deployment of the stent within the main pancreatic duct (blue arrowhead). To minimize technical bias and ensure safety, all procedures in this study were performed by a single senior chief physician (one of the corresponding authors) with extensive expertise in pancreatic cannulation, who performs over 1,000 endoscopic procedures annually.

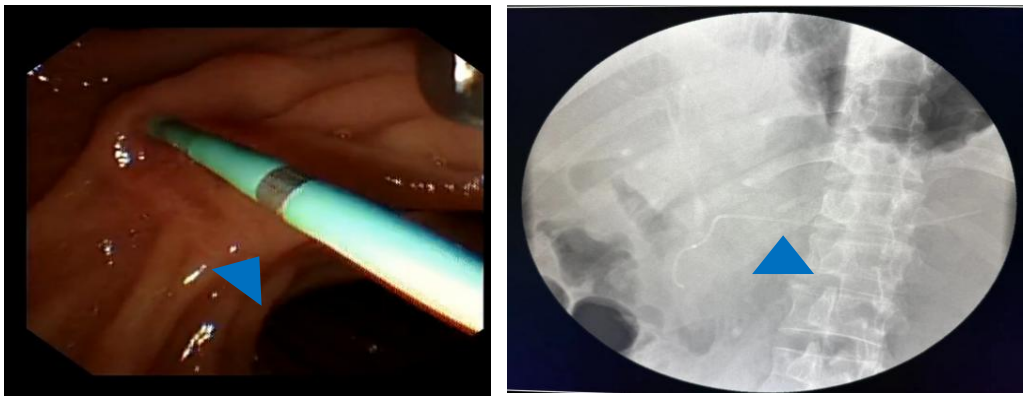


Figure.1 Endoscopic and fluoroscopic images of pancreatic duct stent placement.
(Left) Endoscopic view showing the deployment of a 5Fr plastic stent through the major duodenal papilla (blue arrowhead). (Right) Fluoroscopic image confirming the proper positioning of the stent within the main pancreatic duct (blue arrowhead).

Regarding the timing of endoscopic intervention, for patients with moderately severe and severe acute pancreatitis, earlier intervention yields better therapeutic outcomes. Delaying intervention until the mid-to-late severe stage presents the following challenges: (1) patients may be unable to tolerate procedural anesthesia, leading to elevated anesthetic risk; and (2) severe intestinal edema impedes the advancement of the duodenoscope and restricts the endoscopic field of view, thereby substantially increasing the technical difficulty of the procedure.

2. Sample Size Calculation

Sample size was estimated according to the convention for multiple linear regression analysis, whereby the required sample is 5–10 times the number of variables. In this study, the general information questionnaire comprised 13 items, the Chinese version of the Pancreatitis Quality of Life Instrument (PANQOLI) comprised 4 dimensions, and the General Comfort Questionnaire (GCQ) comprised 4

dimensions, yielding a total of 21 variables. To account for sampling error and potential loss to follow-up, the estimated sample size was inflated by 20%, giving a target range of 126–252 cases. A total of 146 patients were ultimately enrolled.

3. Survey Instruments

3.1 General Information Questionnaire for AP Patients

A general information questionnaire for AP patients was developed based on a review of the literature. It included demographic data (name, age, medical record number, contact information, sex, education level, occupation, and employment status) and disease-related data (number of prior hospitalizations for pancreatitis, etiology, disease severity at admission, whether the stent placement was the patient's first, and whether concurrent biliary intervention was performed). Clinical data at each time point were extracted from the hospital's electronic medical record system: admission indicators were collected within the first 24 hours of hospitalization, and discharge indicators within 24 hours before discharge.

3.2 Assessment of Clinical Symptoms after Pancreatic Duct Stent Placement in AP Patients

The Pancreatitis Quality of Life Instrument (PANQOLI), developed through a multicenter study in the United States, is a disease-specific instrument for assessing quality of life in patients with pancreatitis [26]. Wassef et al. [27] evaluated its reliability and validity in 159 patients with pancreatitis, reporting a Cronbach's α of 0.914, indicating good psychometric performance. Relative to generic instruments, the scale's most distinctive feature is a dedicated "self-worth" module, which confers greater specificity and sensitivity for evaluating quality of life in this population. Aivaliotis et al.[28] applied the PANQOLI to assess the effect of psychological intervention on quality of life in patients with pancreatitis and found that intervention effects captured by the PANQOLI corresponded closely with those captured by the mental component of the SF-36.

The Chinese version of the PANQOLI was developed by Wang Yuanchen in 2023 [29]. Its average content validity index was 0.91, and the Cronbach's α of the total scale was 0.868, with a positive correlation with the SF-36—indicating good

reliability and validity for assessing quality of life in this population. The Chinese version comprises 4 dimensions and 18 items. Physical function (items 1–6) captures changes in pain, vomiting, nausea, diarrhea severity, weight loss, and sleep quality. Role function (items 7–10) captures the ability to participate in household or family activities, social activities, work or study, and travel or vacation. Emotional function (items 11–14) captures changes in frustration or depression, anxiety or worry, irritability or anger, and loneliness or isolation. Self-worth (items 15–18) captures satisfaction with self-image, perceived burden on family or others, confidence about the future, and perceived loss of control over one's life. Each item is scored from 0 to 5, with items 1–6 and 12–18 reverse-scored. Total scores range from 0 to 90, with higher scores indicating better quality of life.

PANQOLI was originally developed for chronic pancreatitis rather than acute pancreatitis. For this study, the investigators retained the 18 items and scoring rules but changed the recall anchors at each assessment: admission relative to the pre-illness state, pre-discharge relative to the pre-procedure state, and 2-week follow-up relative to disease onset. Expert review assessed face/content suitability but did not establish construct validity, responsiveness, measurement invariance, or comparability across the three modified recall periods. Consequently, this adapted instrument should be described as an exploratory, nonvalidated AP adaptation, not as a validated measure of AP quality of life. Its large score changes may partly reflect differences in recall framing and response context.

3.3 Assessment of Comfort after Pancreatic Duct Stent Placement in AP Patients

Comfort was assessed using the General Comfort Questionnaire (GCQ), developed by American nursing scholar Kolcaba [30] on the basis of her taxonomic model of comfort. The instrument was progressively refined under her "comfort theory," established in 1994, and has since become a key tool linking nursing theory to clinical practice.

The GCQ was translated into Chinese and psychometrically validated by Zhu Lixia in 2004 [31], yielding a content validity index of 0.86 and a Cronbach's α of 0.92, indicating good reliability and validity for assessing patient comfort. The Chinese

version comprises 4 dimensions and 30 items: physical (items 2, 9, 13, 16, 17), psychological (items 3, 4, 5, 12, 15, 18, 22, 24, 26, 28), social (items 1, 6, 8, 10, 23, 25, 29, 30), and environmental (items 7, 11, 14, 19, 20, 21, 27). Items are rated on a 4-point Likert scale from 1 (strongly disagree) to 4 (strongly agree), with reverse-scored items (e.g., "I feel depressed") handled accordingly. Total scores range from 30 to 120, with higher scores indicating greater comfort.

4. Data Collection Procedures

Baseline data, including general and disease-related characteristics, were first extracted from the hospital's electronic medical record system and supplemented by the research team. The study's purpose, significance, and procedures were then explained to patients in person. After obtaining informed consent, patients were instructed on how to complete the questionnaires, which were distributed on-site and collected after verification. Questionnaires were completed by patients themselves or, where necessary, by their caregivers; for patients with limited literacy or impaired vision, the researcher recorded responses as dictated by the patient.

To ensure completion quality and response rate, paper-based questionnaires were used throughout the in-hospital phase. These were administered face-to-face by the researcher at the bedside within 24 hours of admission and within 24 hours before discharge, with the purpose and instructions for each survey explained beforehand. At 2 weeks post-discharge, an online questionnaire was administered by the researcher via WeChat or telephone follow-up.

All questionnaires were checked and collected on-site, with missing items completed immediately. Of 150 questionnaires distributed, 4 were excluded as invalid, leaving 146 valid questionnaires and an effective response rate of 97.33%.

5. Quality Control

Prior to data collection, the principal investigator underwent training by the study supervisor to ensure procedural consistency. Issues arising during the survey process were reviewed and resolved in a standardized manner. Data entry was performed by the investigator and independently verified by a second author to ensure accuracy and completeness before the SPSS database was finalized.

6. Statistical Analysis

All data entry and statistical analyses were performed using SPSS 29.0. Categorical variables were expressed as frequencies and percentages. Continuous variables were assessed for normality; normally distributed data are presented as mean ± standard deviation (SD), and non-normally distributed data as median and interquartile range (IQR).

One-way repeated-measures analysis of variance (ANOVA) or the Friedman test was applied to evaluate longitudinal changes in PANQOLI scores, GCQ scores, and individual symptom and emotion indicators across the three time points (admission, before discharge, and 2 weeks post-discharge). The magnitude of change in each inflammatory marker and in subjective symptom, quality-of-life, and comfort scores during hospitalization was quantified as a change score (discharge value minus admission value). Pearson or Spearman rank correlation analysis was used to assess linear correlations between the changes in objective inflammatory indicators and the improvements in PROs, depending on data distribution. One-way ANOVA was used to compare short-term recovery indicators among AP patients with different etiologies. A two-sided $P<0.05$ was considered statistically significant.

RESULTS

1. Comparative Analysis of Baseline Characteristics by Etiology in Patients Undergoing Endoscopic Pancreatic Duct Stent Placement

A total of 146 patients who underwent pancreatic duct stent placement were included in this study, comprising 62 cases of biliary AP (42.5%), 56 cases of hypertriglyceridemic AP (38.4%), and 28 cases of other-etiology AP (19.2%). The baseline characteristics and disease severity of the participants are summarized in Table 1. Statistically significant differences were observed among the three etiology groups in terms of age ($P=0.001$), sex ($P=0.021$), educational level ($P=0.004$), and disease severity (). Notably, while the majority of patients had moderately severe or severe AP, a total of 7 patients (4.8%) presented with mild AP (1 biliary, 1

hypertriglyceridemic, and 5 other-etiology). These 7 mild AP patients received pancreatic duct stenting primarily due to the presence of prominent abdominal pain and distension, which aligned with the clinical selection criteria for the procedure. Regarding procedural safety, no adverse events related to the defined safety indicators---specifically post-ERCP pancreatitis exacerbation, ERCP-related bleeding, perforation, or pancreatobiliary injury—were observed in this cohort.

Table 1 Baseline characteristics of participants with different etiologies of acute pancreatitis (N=146,%)

Item	Classification	Biliary AP (n=62)	Hypertriglyceridemic AP (n=56)	Other-etiology AP (n=28)	Statistical value	*P* value
	Age (years)	62.00 [47.75, 73.25]	37.00[33.00, 46.00]	46.00 [38.00, 57.75]	44.485	0.001**
Sex	Male (100,68.5%)	35(35.0)	42(42.0)	23(23.0)	7.682	0.021*
	Female (46, 31.5%)	27(58.7)	14(30.4)	5(10.9)		
Educational level	Primary school and below (41, 28.1%)	28(68.4)	9(22.0)	4(9.6)		
	Junior high school (39, 26.7%)	14(35.9)	15(38.5)	10(25.6)		
	High school/Technical secondary school (30, 20.5%)	12(40.0)	11(36.7)	7(23.3)	22.263	0.004*
	Junior college (10, 6.8%)	4(40.0)	4(40.0)	2(20.0)		
	Bachelor's degree and above (26, 17.8%)	4(15.4)	17(65.4)	5(19.2)		
Disease severity	Mild (7, 4.8%)	1(14.3)	1(14.4)	5(71.3)		
	Moderate-severe (94, 64.4%)	42(44.7)	36(38.3)	16(17.0)	13.152	0.001**
	Severe (45, 30.8%)	19(42.2)	19(42.2)	7(15.6)		
First-time pancreatic stent placement (72, 49.3%)		42(58.3)	24(33.3)	6(8.4)	18.068	0.001**
Biliary tract intervention performed (56, 38.4)		46(82.1)	9(16.1)	1(1.8)	59.768	0.001**
Self-perceived disease recovery	Very good (118, 80.8%)	48(40.7)	46(39.0)	24(20.3)	0.959	0.619
	Good (28, 19.2%)	14(50.0)	10(35.7)	4(14.3)		
Dietary recovery	Very good (11,7.5%)	3(27.3)	5(45.4)	3(27.3)	1.908	0.753

status	Good (107,73.3%)	45(42.1)	41(38.3)	21(19.6)		
	Fair(28,19.2%)	14(50.0)	10(35.7)	4(14.3)		
Discharge with drainage tube (9,6.1%)		5(55.6)	3(33.3)	1(11.1)	0.776	0.679

*: ***P*<0.05**, **: ***P*<0.001.**

2. Comparative Analysis of Inflammatory Indicators and Postoperative Recovery Parameters by Etiology at Different Time Points After Endoscopic Pancreatic Duct Stent Placement

Comparisons of inflammatory laboratory indicators between admission and discharge for all patients are presented in Table 2. Compared with admission values, serum amylase, serum lipase, white blood cell count, and C-reactive protein (CRP) were all significantly lower before discharge (all $P<0.05$), whereas the change in serum procalcitonin did not reach statistical significance ($P=0.057$).

Between-group comparisons of short-term postoperative outcomes among patients with biliary AP, HTG-AP, and AP of other etiologies are presented in Table 3. No significant differences were observed among the three groups in postoperative pain relief time, total or postoperative length of hospital stay, or time to first postoperative oral intake (all $P>0.05$). These findings indicate that patients with AP of differing etiologies achieve comparable therapeutic benefit from endoscopic pancreatic duct stent placement, lending further support to the clinical value, feasibility, and generalizability of this procedure in the management of AP.

Table 2 Comparison of inflammatory biomarkers among participants at different time points (N=146, $\bar{x}\pm s$)

Inflammatory biomarkers	At admission	Before discharge	Statistical value	*P* value
Serum amylase (U/L)	658.46±808.77	83.74±65.45	62.234	＜0.001
Serum lipase (U/L)	5285.62±6922.52	448.29±601.87	62.773	＜0.001
White blood cell count (×10^9/L)	10.96±5.23	7.59±3.04	66.796	＜0.001
CRP(mg/L)	82.20±118.65	41.94±48.46	9.850	0.002
Serum procalcitonin (ng/mL)	2.70±10.84	0.67±2.70	3.717	0.057

Table 3 Comparison of post-operative efficacy indicators among participants with different etiologies of acute pancreatitis (N=146, $\bar{x}\pm s$)

Indicators	Biliary AP (n=62)	Hypertriglyceridemic AP (n=56)	Other-etiology AP (n=28)	Statistical value	*P* value
Post-operative pain relief time (h)	24.00 [12.00,24.00]	24.00 [12.00,24.00]	12.00 [6.00,24.00]	2.715	0.257
Time to first postoperative dietary resumption (h)	40.65±22.49	37.61±24.63	35.32±31.08	0.485	0.617
Post-operative hospital stay (d)	5.05±3.07	4.71±3.00	3.75±3.90	1.577	0.210
Total hospital stay (d)	6.50±3.25	6.32±3.58	5.00±3.79	1.906	0.152

Note: Median [interquartile range] was presented for non-normally distributed variables; normally-distributed data were expressed as mean ± standard deviation.

3 Changes in Quality of Life and Related Symptoms Following Endoscopic Pancreatic Duct Stent Placement at Different Time Points

3.1 Changes in Total Quality of Life Scores

The PANQOLI was used to evaluate quality of life at three time points—admission, before discharge, and 2 weeks post-discharge. Dimension and total scores at each time point are presented in Table 4. Total PANQOLI scores increased steadily over time, rising from 19.84 at admission to 82.23 at 2 weeks post-discharge ($P<0.001$). Scores in all four dimensions—physical function, role function, emotional function, and self-worth—showed similarly significant upward trends across time points ($P<0.001$) (Fig. 2), demonstrating a significant longitudinal improvement in patient-reported quality of life during the short-term recovery period.

Table 4 Comparison of PANQOLI sub-domain scores of participants at different time points (N=146, $\bar{x}\pm s$)

Sub-domain	At admission	Before discharge	2-week post-discharge	Statistical value	*P* value
Physical function	6.79±2.04	24.17±1.48	28.83±0.50	9856.084	＜0.001
Role function	4.75±1.43	13.06±1.53	17.92±1.62	3075.437	＜0.001
Emotional function	3.72±2.10	15.47±0.77	17.66±0.78	4480.219	＜0.001

Self-worth	4.59±1.61	15.34±1.14	17.82±0.78	5229.293	＜0.001
Total score	19.84±3.92	68.04±2.93	82.23±2.35	18756.104	＜0.001

Data are presented as mean±standard deviation. Repeated-measures analysis of variance was applied for inter-time-point comparison. $P<0.001$ indicates statistically significant difference.

3.2 Comparative Analysis of Changes in Acute Pancreatitis-Related Symptoms and Emotions at Different Time Points

Changes in pancreatitis-related symptoms and negative emotions were compared across the three time points — admission, before discharge, and 2 weeks post-discharge. Repeated-measures ANOVA revealed significant time effects for all symptom and emotion scores over the course of treatment ($P<0.001$). Post-hoc comparisons showed that scores for pain, vomiting, nausea, and diarrhea, as well as for the negative-emotion subdomains of depression-frustration, anxiety-worry, and irritability-anger, were all significantly higher before discharge and at 2 weeks post-discharge than at admission—reflecting improvement, given the reverse-scored convention of these items. These findings indicate that endoscopic pancreatic duct stent placement effectively alleviates disease-related discomfort and improves associated negative emotions, as detailed in Table 5.

Table 5 Comparison of AP-related symptoms and emotional changes among participants at different time points (N=146, $\bar{x}\pm s$)

Item	At admission	Before discharge	2-week post-discharge	Statistical value	*P* value
Symptom changes					
Pain severity	0.21±0.41	4.92±0.27	4.96±0.20	12265.646	＜0.001
Vomiting severity	0.96±0.66	4.91±0.29	4.97±0.16	4331.723	＜0.001
Nausea severity	0.91±0.67	4.87±0.41	4.97±0.18	3579.748	＜0.001
Diarrhea severity	1.97±1.30	4.89±0.31	4.97±0.16	730.381	＜0.001
Emotional changes					
Depression-frustration severity	1.07±1.14	3.89±0.31	4.07±0.25	801.763	＜0.001
Anxiety-worry severity	0.43±0.50	3.84±0.37	4.00±0.33	3874.924	＜0.001
Irritability-anger severity	0.94±0.67	3.86±0.35	4.84±0.38	2676.975	＜0.001

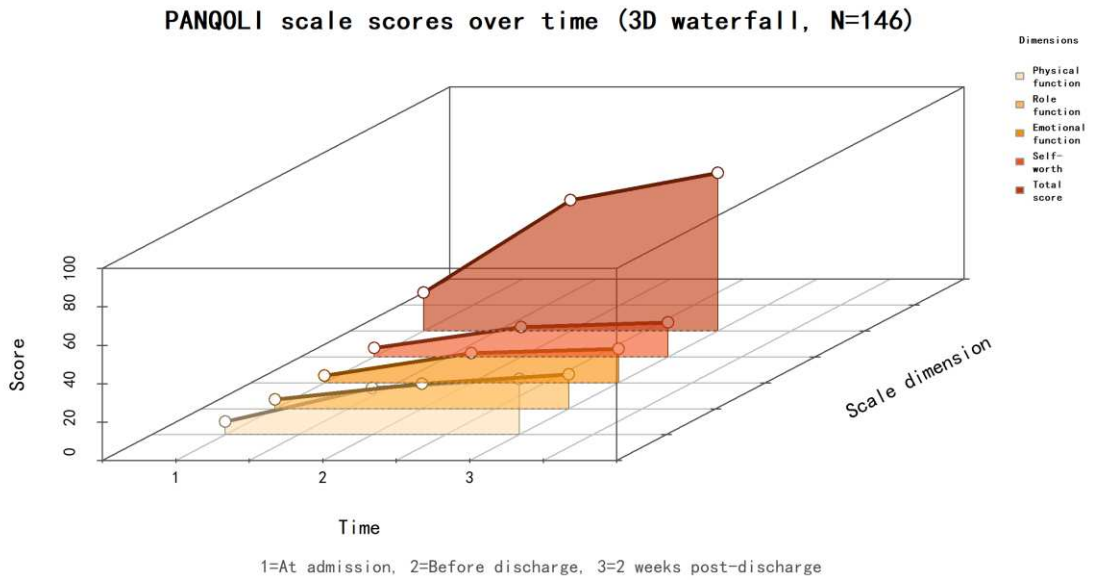


Figure 2 Changes in PANQOLI scale scores at different assessment time-points among patients receiving endoscopic pancreatic stent placement (N = 146).

This 3-D waterfall plot visualizes score variations across four sub-domains (physical function, role function, emotional function, self-worth) and the total quality-of-life score. Time-point 1 denotes admission, time-point 2 indicates pre-discharge evaluation, and time-point 3 corresponds to the 2-week short-term follow-up after hospital discharge. Repeated-measures analysis of variance identified a significant main effect of time for all PANQOLI sub-domain and total scores ($P < 0.001$), showing progressive elevation in patient-reported quality-of-life scores across these three time-points.

4. Changes in GCQ Comfort Scale Scores at Different Time Points Following Endoscopic Pancreatic Duct Stent Placement

Repeated-measures ANOVA was used to compare GCQ scores at admission, before discharge, and 2 weeks post-discharge; results are presented in Table 6. Significant time effects were observed for the total GCQ score and for the physical, psychological, social, and environmental dimension scores (P<0.001). The total GCQ score increased progressively, from 57.82±3.35 at admission to 93.51±3.31 before discharge, and further to 103.55±2.42 at 2 weeks post-discharge. Scores in all four dimensions likewise showed a steady upward trend (Fig.3), reflecting a progressive enhancement in patient comfort across the three assessment time points.

Table 6 Comparison of GCQ sub-domain scores of participants at different time points

(N=146, $\bar{x}\pm s$)

Sub-domain	At admission	Before discharge	2-week post-discharge	Statistical value	*P* value
Physiological domain	7.88±1.27	16.10±0.92	18.67±0.86	4291.312	＜0.001
Psychological domain	19.73±1.38	30.95±1.26	34.47±1.22	5116.861	＜0.001
Social domain	17.32±1.74	24.36±2.02	27.01±1.32	1197.874	＜0.001
Environmental domain	12.89±1.39	22.10±1.80	23.40±1.30	2104.306	＜0.001
Total score	57.82±3.35	93.51±3.31	103.55±2.42	7985.350	＜0.001

Data are expressed as mean ± standard deviation. Repeated-measures analysis of variance was used for comparisons across different time points. $P < 0.001$ was considered statistically significant.

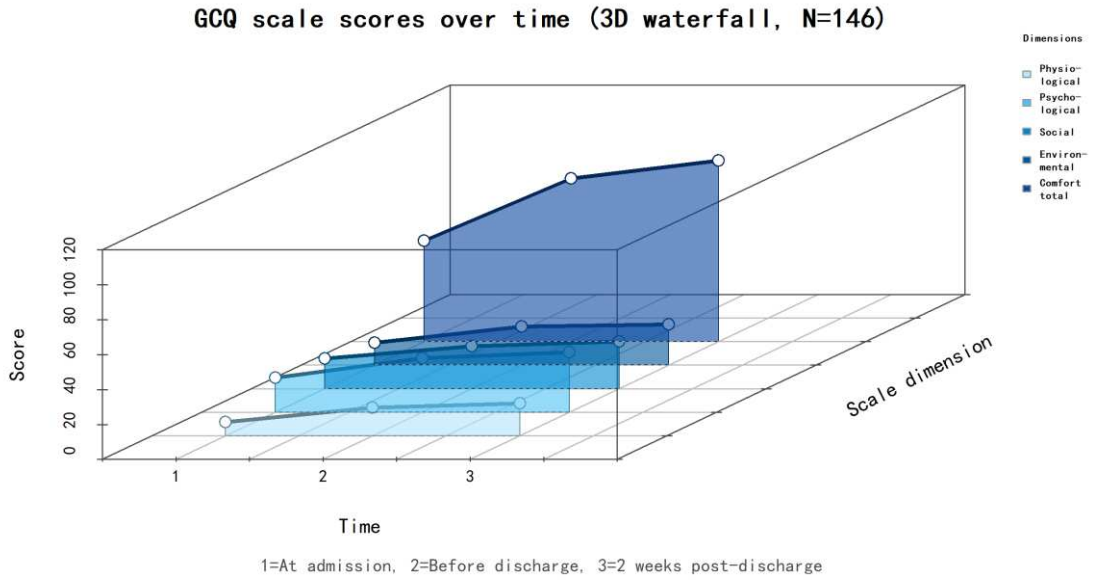


Figure 3 Changes in General Comfort Questionnaire (GCQ) scores across three assessment time-points among participants who underwent endoscopic pancreatic stent placement (N = 146).

This 3-D waterfall plot visualizes the longitudinal score variations for four sub-domains (physiological, psychological, social, environmental) and the total comfort score. Time-point 1 indicates admission, time-point 2 represents pre-discharge evaluation, and time-point 3 corresponds to two-week follow-up after hospital discharge. Repeated-measures analysis of variance revealed a significant main effect of time for all GCQ sub-domain and total scores (P<0.001), with comfort scores gradually elevated over the clinical course.

5. Correlation Analysis Between the Magnitude of Decrease in Inflammatory Markers and Improvement in Subjective Perceptions

To examine the relationship between improvement in objective inflammatory indicators and change in patient-reported outcomes, Pearson correlation analysis was used to assess associations between the magnitude of decrease in serum amylase, lipase, C-reactive protein (CRP), procalcitonin (PCT), and white blood cell (WBC) count, and the magnitude of improvement in PANQOLI scores, GCQ scores, and relief of individual subjective symptoms. Results are presented in Table 7 and Fig.4.

The magnitude of decrease in amylase and lipase showed no significant correlation with improvement in PANQOLI or GCQ scores, or with relief of any subjective symptom (all $P>0.05$). The decrease in CRP was weakly and negatively correlated with improvement in GCQ scores ($r=-0.24$, $P<0.05$) but was not significantly associated with improvement in PANQOLI scores ($P>0.05$). The decrease in PCT showed a weak negative correlation with relief of vomiting ($r=-0.20$, $P<0.05$) and a weak positive correlation with relief of diarrhea ($r=0.23$, $P<0.05$). The decrease in WBC count showed only a weak positive correlation with relief of irritability/anger ($r=0.23$, $P<0.05$). All statistically significant correlation coefficients were low in absolute value, indicating weak associations.

Taken together, although patients showed marked improvement in inflammatory laboratory indicators, subjective symptoms, quality of life, and comfort following endoscopic pancreatic duct stent placement, no significant overall linear association was observed between the magnitude of decrease in inflammatory markers and the overall improvement in quality of life or comfort; only a few inflammatory markers showed weak correlations with a limited number of individual symptoms.

These findings suggest that the recovery of objective laboratory parameters and the improvement in patients' subjective perceptions represent partially divergent dimensions of the recovery trajectory. The subjective benefits reported by patients cannot be fully explained by reductions in inflammatory markers alone, highlighting the necessity of incorporating PROs into the efficacy evaluation framework for this off-guideline practice.

Table 7 Pearson correlation matrix for the reduction range of objective inflammatory indicators and improvement range of subjective outcomes in participants (N=146, r)

Variable	GCQ Scale improvement	PANQOLI Scale improvement	Pain relief range	Vomiting relief range	Nausea relief range	Diarrhea relief range	Depression relief range	Anxiety relief range	Irritability relief range
Amylase reduction	-0.02	0.01	-0.09	-0.02	0.06	-0.11	0.18	-0.13	0.09
Lipase reduction	0.04	-0.02	-0.15	0.01	-0.04	-0.02	0.17	-0.10	0.15
CRP reduction	-0.24*	-0.11	0.16	-0.09	0.09	-0.03	-0.01	-0.01	0.00
PCT reduction	0.05	0.11	-0.07	-0.02*	-0.08	0.23*	-0.04	0.00	0.11
WBC reduction	0.16	0.07	-0.08	0.08	0.06	0.14	0.07	-0.07	0.23*

Note. Pearson's correlation coefficients (r) are presented in cells. N=146. *P<0.05, two-tailed. All pairwise correlations were tested via two-tailed Pearson correlation analysis.

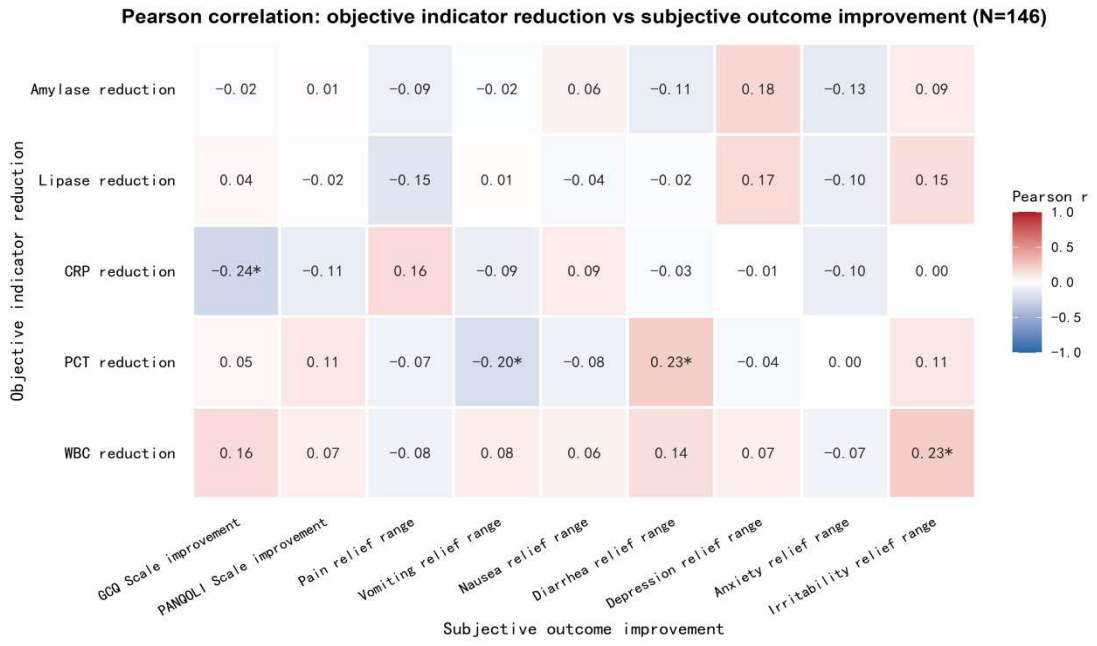


Figure 4 Heatmap of Pearson correlation coefficients between the reduction range of objective inflammatory indicators and the improvement range of patient-reported subjective outcomes.

Pearson's correlation coefficients (r) are displayed within each cell. N=146. * P<0.05, two-tailed test. The color gradient represents the magnitude of correlation coefficients; red indicates positive correlation, and blue indicates negative correlation.

DISCUSSION

In this study, we systematically evaluated dynamic changes in inflammatory markers, symptom burden, quality of life, and comfort from admission through discharge and 2 weeks post-discharge in patients with acute pancreatitis (AP) following endoscopic pancreatic duct stent placement, drawing on patient-reported outcomes (PROs)—including self-reported quality of life, clinical symptoms, and comfort—alongside objective clinical indicators (serum amylase, CRP, and white blood cell count). In this cohort, patients receiving pancreatic duct stents demonstrated significant longitudinal improvements in both objective inflammatory indicators and patient-reported outcomes (quality of life and comfort). The observation of similar recovery trajectories across biliary, hypertriglyceridemic, and other etiologies suggests a consistent short-term recovery pattern in this selected population.

1. Etiological Composition and Clinical Characteristics of the Study Population

The etiological composition of AP exhibits marked population-level heterogeneity. Among the 146 patients enrolled in this study, biliary AP was the most common etiology (42.47%), followed by hypertriglyceridemic AP (38.36%)—a distribution broadly consistent with the etiological spectrum described in domestic AP clinical practice guidelines [1, 32].

Baseline characteristics also differed markedly by etiology: patients with biliary AP were generally older, more often female, and had lower educational attainment on average, whereas patients with hypertriglyceridemic AP were predominantly young to middle-aged males. This pattern aligns with findings from several regional population-based studies in China and elsewhere [4, 33]. In a study of 500 AP patients, biliary etiology was significantly more common among females than males ($P<0.05$), while hypertriglyceridemic etiology remained relatively prevalent across both sexes [34]. A retrospective cohort of 702 AP patients likewise reported significant differences in sex, age, and body mass index across etiological subgroups [35]. Mechanistically,

biliary pancreatitis is predominantly driven by gallstones or biliary obstruction and occurs more often in middle-aged and elderly women, whereas hypertriglyceridemia-associated pancreatitis is more common among young and middle-aged men and is closely linked to metabolic dysfunction and unhealthy lifestyle factors [36-38]. These demographic differences point to the need for etiology-tailored health education and disease management strategies in clinical practice.

Notably, self-perceived disease recovery and dietary recovery status at discharge did not differ significantly among the three etiological subgroups. This finding suggests that, despite substantial differences in demographic background and objective clinical presentation during hospitalization, patients with different AP etiologies tend to converge on a comparable subjective recovery experience by the time of discharge following standardized inpatient treatment such as endoscopic pancreatic duct stent placement. This convergence offers a practical rationale for using patient-reported outcome measures to evaluate this procedure's efficacy, and underscores that clinical efficacy assessment should give equal weight to patient-reported outcomes—subjective symptoms, quality of life, and comfort—alongside traditional objective indicators such as laboratory and imaging findings.

2. Improvement in Quality of Life, Symptom Burden, Emotional Well-Being, and Comfort

Quality of life and treatment comfort are core patient-reported outcomes and important dimensions for evaluating the efficacy of pancreatic duct stent placement. As the traditional biomedical model—focused narrowly on biological indicators—gives way to a biopsychosocial model encompassing psychological and social functioning, PROs have emerged as a key tool embodying patient-centered care [39-40]. Because PROs capture health status and treatment experience directly from the patient, without interpretation by clinicians or third parties, they can reflect functional status and subjective experience that traditional objective measures often fail to

quantify [41-42]—providing the theoretical rationale for using the PANQOLI and GCQ instruments in this study.

Across the three time points assessed (admission, before discharge, and 2 weeks post-discharge), PANQOLI total scores and all four dimension scores—physical function, role function, emotional function, and self-worth—increased continuously following stent placement. Physical symptoms including pain, nausea, vomiting, and diarrhea were significantly relieved, and negative emotions such as depression, anxiety/worry, and irritability/anger improved markedly. GCQ total comfort scores and scores across the physical, psychological, social, and environmental dimensions showed a corresponding progressive upward trend that persisted through 2 weeks post-discharge. These findings indicate that the therapeutic benefit of pancreatic duct stent placement extends beyond improvement in inflammatory laboratory markers to encompass synchronous, multi-domain gains in physical symptoms, psychological and emotional well-being, and social and environmental adaptation.

During an acute AP episode, severe abdominal pain and gastrointestinal symptoms impose substantial physiological stress; combined with uncertainty about disease prognosis, these factors readily provoke anxiety and depressed mood, directly impairing daily functioning and disrupting normal family and social roles. This is likely an important driver of the low quality-of-life and comfort scores observed early after admission in this cohort [40, 43-44]. In clinical practice, clinicians tend to rely on objective indicators such as serum amylase and CRP to judge treatment efficacy, potentially overlooking patients' subjective experience. It is not uncommon for patients with normalized inflammatory markers to nonetheless report residual abdominal discomfort and significant psychological distress—their subjective recovery lagging behind their laboratory recovery. It is plausible that stent placement may alleviate AP-related physical symptoms by reducing intraductal pressure... This mechanical relief, combined with the natural resolution of the acute inflammatory episode over time, may have contributed to the observed improvements in quality of life and comfort.

Temporally, PANQOLI and GCQ scores across all dimensions continued to improve from discharge through 2 weeks post-discharge, indicating that physical and psychological recovery does not end at hospital discharge and that the post-discharge period remains a critical window for subjective recovery. Restoration of physical function enables resumption of daily activities; improved role function reflects a gradual return to family and social roles; rising psychological scores signal effective relief of negative emotion; and gains in the social and environmental dimensions represent patients' re-adaptation to their family and living environment.

This study's follow-up, however, extended only to 2 weeks post-discharge—a short-term observation window that constitutes a limitation of this analysis. Prior studies have shown that patients with moderately severe or severe AP may develop long-term complications such as diabetes mellitus and pancreatic exocrine insufficiency, leading to a sustained decline in quality of life[45-46], and such complications may similarly affect comfort over an extended period[47]. Clinical management should therefore not end with symptom control during hospitalization; continued attention to patients' physical symptoms, psychological status, and comfort after discharge—supported by appropriate follow-up care—remains essential. These findings underscore the value of patient-reported outcomes in capturing the full spectrum of recovery. Future controlled studies are warranted to determine whether incorporating PROs into routine AP efficacy assessment frameworks can optimize patient-centered care [48].

3. Relationship Between Objective Inflammatory Markers and Patient-Reported Outcomes

The findings above confirm that endoscopic pancreatic duct stent placement effectively reduces systemic inflammation while significantly improving quality of life, physical symptoms, negative emotions, and comfort. Whether these objective biological changes bear a direct linear relationship to improvement in subjective outcomes, however, warranted further investigation. Pearson correlation analysis revealed no significant correlation between the magnitude of decrease in serum

amylase or white blood cell count and the magnitude of improvement in PANQOLI or GCQ scores, or with most symptom-relief indicators. Only a handful of weak associations emerged: the decrease in CRP was weakly and negatively correlated with GCQ improvement; the decrease in PCT showed weak correlations with relief of vomiting and diarrhea; and the decrease in WBC count was weakly correlated with relief of irritability/anger—though all statistically significant coefficients were low in absolute value. Overall, no stable linear relationship was observed between the magnitude of decrease in inflammatory markers and improvement in total quality-of-life or comfort scores. This finding suggests that normalization of inflammatory markers does not equate to proportional, synchronous improvement in patients' subjective experience, and that recovery of objective laboratory parameters and improvement in patient-reported outcomes constitute two relatively independent dimensions of treatment efficacy.

In clinical practice, decline in inflammatory markers is often treated as the principal basis for judging treatment efficacy, with the implicit assumption that greater biochemical improvement corresponds to better subjective recovery. Our findings do not support this assumption. The decrease in inflammatory markers primarily reflects the biological process of controlling pathological injury, whereas patients' subjective experience is shaped not only by the underlying pancreatic pathology but also by non-biological factors—individual pain tolerance, psychological coping style, illness perception, and family and social support[49-52]. Similar dissociations have been reported elsewhere[40, 53]: some patients with excellent biochemical recovery continue to experience persistent dull abdominal pain and anxiety with little improvement in quality of life, while others with only modest biochemical improvement report marked gains in physical comfort and psychological well-being.

This dissociation indicates that inflammatory laboratory markers alone cannot fully capture the therapeutic benefit of endoscopic pancreatic duct stent placement. The procedure exerts its effect by relieving pancreatic duct obstruction and reducing intraductal pressure through two partially distinct pathways: suppression of the

pancreatic inflammatory cascade, reflected in improved laboratory markers [14], and direct relief of obstruction-related physical symptoms such as pain, which confers subjective benefit independently. Because these two pathways of benefit do not fully overlap, improvement in inflammatory markers need not track linearly with improvement in subjective outcomes.

CONCLUSION

In this cohort of patients receiving endoscopic pancreatic duct stents as part of multimodal AP care, significant short-term improvements were observed in objective inflammatory markers, self-reported quality of life, comfort, and symptom burden. Similar recovery trajectories were noted across different AP etiologies in our single-center setting. Notably, the lack of a strong correlation between the magnitude of inflammatory marker reduction and subjective improvement highlights that these two metrics capture distinct dimensions of the recovery process—pathological resolution versus the patient's lived experience. These exploratory findings underscore the value of incorporating PROs into efficacy assessment frameworks to complement traditional objective indicators. Future controlled studies are warranted to confirm the clinical efficacy of this off-guideline practice and to inform its potential role in standardized AP management.

Comparison with Previous Studies

Our previous large-scale retrospective analyses provided robust preliminary evidence for the clinical feasibility of early pancreatic stenting in AP [14-15]. While those studies primarily focused on objective clinical endpoints (e.g., hospital stay, organ failure), the current study was specifically designed to address a distinct gap: the longitudinal evaluation of patient-reported subjective recovery. The longitudinal PROs data reported here complement our previous objective findings, collectively constructing a multidimensional evidence base for this off-guideline intervention.

Limitations

Several limitations should be acknowledged. First, this was a single-center, single-arm observational study without a parallel control group. The observed improvements in both objective and subjective indicators may partly reflect the natural recovery of AP, the Hawthorne effect, or the additional attention patients received during the study. Second, the sample was recruited via convenience sampling from a specialized hepatobiliary surgical center, which may limit the generalizability of the findings to broader AP populations. Third, the PANQOLI instrument was adapted for AP in this study with modified recall anchors, lacking formal psychometric validation for this specific context; thus, changes in scores may partly reflect response shifts. Finally, the follow-up period was limited to 2 weeks post-discharge, preventing assessment of long-term PRO trajectories. Therefore, the findings should be interpreted as exploratory and hypothesis-generating.

Ethics Statement

This study was approved by the Ethics Committee of the General Hospital of Ningxia Medical University (Approval No. KYLL-2023-0509) and was conducted in accordance with the Declaration of Helsinki. The purpose and significance of the study were explained in detail to all patients, who were informed that questionnaires would not contain identifying names, and voluntary participation was confirmed through full informed consent. Survey data were coded using Arabic numerals only, and all collected data were used exclusively for statistical analysis. Patients' personal information was kept strictly confidential to protect their privacy.

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Conflict of Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Availability of data and materials

The datasets generated during and/or analysed during the current study are available from the first author and corresponding author on reasonable request.

The data are not publicly available due to restrictions [e.g. their containing information that could compromise the privacy of research participants].

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Authors' contributions

Y.Y. and W.Y. contributed equally to this work and share first authorship. Z.W. and B.L. contributed equally to this work and share corresponding authorship, and Z.W.contributed as the primary operating surgeon, performing all endoscopic

pancreatic duct stent placement procedures and providing clinical expertise.

Y.Y. and Z.W. were responsible for the conception and design of the study and secured funding for the project. B.L., J.W., and B.Y. were responsible for the design and analysis of the study instruments. X.W. and Z.M. were responsible for participant recruitment and for data collection and entry at each time point. Y.Y., W.Y., B.L., and Z.W. were responsible for data quality control and for the evaluation and revision of the adaptively modified PANQOLI instrument. Y.Y. drafted the initial manuscript. W.Y., Z.W., and B.L. critically revised the manuscript for important intellectual content. Z.W. and B.L. supervised the study and provided overall project administration. All authors read, critically reviewed, and approved the final manuscript.

All authors have read and agreed to the published version of the manuscript.

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