

Comparison of pancreatic function and quality of life between patients with infected pancreatitis necrosis undergoing open necrosectomy and minimally invasive drainage: A long-term study

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Abstract. The present study aimed to determine whether a difference in pancreatic function and quality of life (QoL) is present between patients with infected pancreatitis necrosis (IPN) undergoing open necrosectomy (ON) and minimally invasive drainage (MID). The medical records of patients with IPN discharged from Jinling Hospital were retrospectively analyzed. Pancreatic function and QoL were compared between patients treated with ON and MID. Pancreatic endocrine and exocrine function were assessed using the oral glucose tolerance test and fecal elastase-1 (FE-1) test, respectively. The standard Short Form 36 health questionnaire was used to evaluate the QoL of patients. The analysis included 101 patients who underwent either ON (n=40, 39.6%) or MID (n=61, 60.4%). There were no significant differences in exocrine and endocrine pancreatic function between the two groups evaluated based on FE-1, fasting blood glucose, glycated hemoglobin and 2-h plasma glucose (P<0.05). The scores of the QoL questionnaire were significantly higher in patients treated with MID than in patients treated with ON, including the scores of general health perception (19.39±3.07 vs. 17.37±3.63, P=0.003), vitality (18.93±2.88 vs. 17.57±3.47, P=0.035), social role functioning (8.85±1.43 vs. 8.15±1.98, P=0.042), emotional role functioning (5.33±1.07 vs. 4.82±1.25, P=0.034), mental health (24.21±3.31 vs. 22.57±3.91, P=0.026) and the total QoL

score (125.12±13.16 vs. 116.50±16.94, P=0.005). In conclusion, although the initial health of the patient may have influenced the treatment provided, patients with IPN who received MID achieved a better post-treatment QoL than those treated with ON. No significant differences between the two groups were observed regarding the endocrine and exocrine functions of the pancreas.

Introduction

An estimated 15-20% of patients with acute pancreatitis (AP) develop necrosis of pancreatic parenchyma and/or peripancreatic necrosis (1,2). Pancreatic necrosis is associated with a mortality rate ranging from 8 to 30% (3). Infected pancreatitis necrosis (IPN) is typically treated by minimally invasive drainage (MID) or open necrosectomy (ON) (2,3). Most studies have demonstrated that ON is associated with high morbidity and mortality (4-11). MID was indicated to decrease mortality without increasing the complications of the infection of infection-associated mortality (12-14). However, to the best of our knowledge, the long-term follow-up of pancreatic endocrine and exocrine function and quality of life (QoL) of patients with IPN has not previously been performed and the difference of pancreatic function and QoL between patients undergoing ON and MID is unknown.

Damaged pancreatic acinar cells may recover after interstitial edematous pancreatitis, improving pancreatic function (15), and complete recovery of pancreatic acinar cells has been documented (16). However, a considerable proportion of patients who recovered from IPN have an impaired endocrine and exocrine pancreatic function (17). Thus, the objective of the present study was to determine the long-term outcomes of patients with IPN treated with ON or MID in terms of pancreatic function and QoL.

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Patients and methods

General information. Patients with IPN who received MID or ON between January 2000 and February 2015 at Jinling

Hospital, Medical School of Nanjing University (Nanjing, China), were included in the present study. The patients were divided into the MID and ON groups based on the interventional approach they received. Demographic data, time spent in the intensive care unit (ICU), the CT severity index (CTSI), Acute Physiology and Chronic Health Evaluation (APACHE) II score and body mass index (BMI) were retrieved from medical records. For all patients, the evaluation of pancreatic endocrine and exocrine function and QoL was performed in May 2016. Written informed consent was obtained from each patient. The protocol of the present study was approved by the ethics committee of Jinling Hospital, Medical School of Nanjing University (Nanjing, China).

The area of pancreatic necrosis was assessed by experienced radiologists based on the necrotic features in the contrast-enhanced CT (CECT) images. IPN was diagnosed on the basis of a positive culture of pancreatic or peripancreatic necrotic tissue obtained from the first drainage procedure or operation or the presence of gas in the fluid collected during CECT.

MID consisted of a sequence of three procedures (18): Percutaneous catheter drainage (PCD), negative pressure irrigation (NPI) and endoscopic necrosectomy (ED) via an artificial sinus tract. Image-guided PCD was considered the first choice for intervention. For this procedure, pigtail tubes were placed using a CT- or ultrasound-guided Seldinger puncture technique in the area of pancreatic necrosis via the retroperitoneum or peritoneum, depending on the location of IPN and adjacent organs (10). NPI was performed using a 'double catheterization cannula' to ensure continuous irrigation of the cavity. ED was performed using a 30F electronic gastroscope inserted through the sinus tract created by double catheterization cannulas and a snare was used to extract out a large volume of necrotic tissue that was difficult to be removed by NPI and PCD.

ON consisted of two steps: First, a laparotomy was performed through bilateral subcostal incisions for blunt removal of the necrotic tissue, and double catheterization cannulas or drainage tubes were then placed for post-operative lavage. The decision to perform ON or MID was made by multidisciplinary discussion between surgeons, internist physician and radiologists, taking into account the area and location of necrosis, abdominal pressure, vital signs and the patient's preference.

Exclusion criteria. The exclusion criteria were as follows: i) Chronic pancreatitis; ii) diagnosis of diabetes mellitus (DM) prior to the IPN episode; iii) chronic diarrhea prior to IPN; iv) intestinal tuberculosis or Crohn's disease; v) family history of DM; vi) incomplete medical records; vii) death during hospitalization or after discharge from hospital; viii) conditions influencing QoL after discharge, including mental diseases, immune system diseases and malignant tumors.

Assessment methods and data collection. Simplified oral glucose tolerance test (19) and fecal elastase-1 (FE-1) test (BIOSERV Diagnostics GmbH) were used to evaluate the pancreatic endocrine and exocrine function, respectively. The data on fasting blood glucose (FBG), free insulin (FINS), fasting C-reactive-peptide, glycosylated hemoglobin (HbA1c), 2-h

plasma glucose (PG), 2-h C-reactive peptide and 2-h insulin, were also collected.

Stool samples were collected for the FE-1 test and stored at -20°C. Concentrations of FE-1 in the stool were interpreted as follows: >200 µg/g stool, normal exocrine pancreatic function; 100-200 µg/g stool, mild to moderate exocrine pancreatic function; <100 µg/g stool, severe exocrine pancreatic dysfunction (20,21).

CT images were used to determine the loss of pancreas of the patients discharged from hospital. The incidence of 100% loss of the pancreas was compared between the MID and ON groups.

The standard short form (SF)-36 questionnaire (22) was used to assess the QoL of patients. SF-36 consists of 8 sections designed to evaluate 8 domains of health, including physical functioning, physical role functioning, bodily pain, general health perceptions, vitality, social role functioning, emotional role functioning and mental health. Patients completed the questionnaire by themselves or with help from their families.

The conversion score of each part of the SF-36 was calculated from the actual score using the following formula (23): Conversion score=(Actual score-Probable lowest score)/Probable highest score-Probable lowest score) x100%.

A higher conversion score indicated a better QoL. The total QoL score was the sum of the scores for each section of the questionnaire.

Statistical analysis. Statistical analysis was performed using SPSS 22.0 for Windows (IBM Corp.). Continuous variables were expressed as the mean ± standard deviation and comparison between groups was performed using Student's t-test. Categorical variables were expressed as absolute numbers and comparison between groups was performed using Fisher's exact test. P<0.05 was considered to indicate a statistically significant difference.

Results

Baseline characteristics. During the enrollment period, 109 patients with IPN were admitted to Jinling Hospital. Of these, 101 patients were included in the present study and 8 were excluded. Among the 8 excluded cases, 6 patients (5.9% of all patients) died during hospitalization or after being discharged from hospital, including 3 who succumbed to septic shock, 2 who died from major bleeding and 1 from unknown causes. Among the patients included, 40 (39.6%) were treated with ON and 61 (60.4%) with MID. There were 66 males and 35 females with a median age of 46 years (interquartile range, 41.5-56.0).

There was no difference between the two groups in terms of age, gender, drinking history, pancreatic necrosis area, positive blood culture, recurrent pancreatitis and the time from discharge to follow-up (Table I). The duration of stay at the ICU in the ON group was longer than that in the MID group (20.28±3.32 vs. 10.36±2.21, P=0.002; Fig. 1). Patients in the MID group required more MID procedures than those in the ON group (P=0.005; Fig. 2). The BMI after discharge was significantly higher in the MID than in the ON group (21.25±3.60 vs. 19.26±2.42, P=0.003; Fig. 3). The incidence of whole pancreatic loss was significantly higher in the ON group (28 vs. 17, P<0.001). The diet, symptoms of diabetes and the

Table I. Clinical characteristics of the patients in the MID group and ON group during their hospital stay.

Variables	MID (n=61)	ON (n=40)	P-value
Age (years)	49.16±1.74	48.65±1.87	0.845
Sex			0.953
Male	40	26	
Female	21	14	
History of drinking			0.485
Present	24	13	
Absent	37	27	
Time interval (months)	35±4.74	37±3.96	0.756
Gallstones			0.244
Present	45	24	
Absent	16	16	
Hypertriglyceridemia			0.161
Present	11	12	
Absent	50	28	
Severity			0.768
Severe	20	12	
Critical	41	28	
APACHE II score	9.89±0.80	12.18±1.06	0.082
Balthazar score	7.37±0.26	7.83±0.28	0.264
Pre-operative infection			0.957
Present	61	40	
Absent	0	0	
BMI (kg/m ²) prior to IPN	27.55±4.32	27.65±3.33	0.905
Duration of ICU stay (days)	10.36±2.21	20.28±3.32	0.002
Organ dysfunction			1.000
Present	40	27	
Absent	21	13	
ARDS			0.404
Present	35	27	
Absent	26	13	
AKI			0.839
Present	28	20	
Absent	33	20	
ACS			0.259
Present	3	5	
Absent	58	38	
Necrotic area ^a			
<1/3	14	12	0.489
1/3-1/2	18	7	0.239
>1/2	29	21	0.686

^aNecrotic area was judged by experienced radiologists based on radiological characteristics of necrosis according to the contrast-enhanced CT images. ON, open necrosectomy; MID, minimally invasive drainage; BMI, body mass index; IPN, infected pancreatitis necrosis; ARDS, acute respiratory distress syndrome; APACHE, Acute Physiology and Chronic Health Evaluation; AKI, acute kidney injury; ACS, abdominal compartment syndrome; time interval, time from discharge to follow-up. Severe acute pancreatitis is defined by the presence of either infected (peri) pancreatic necrosis or persistent organ failure. Critical acute pancreatitis is defined by the presence of infected (peri) pancreatic necrosis and persistent organ failure.

prevalence of pseudocyst and intestinal fistula at the follow-up were similar between the two groups (Table II).

Exocrine and endocrine pancreatic function and QoL. The parameters reflecting the exocrine pancreatic function did

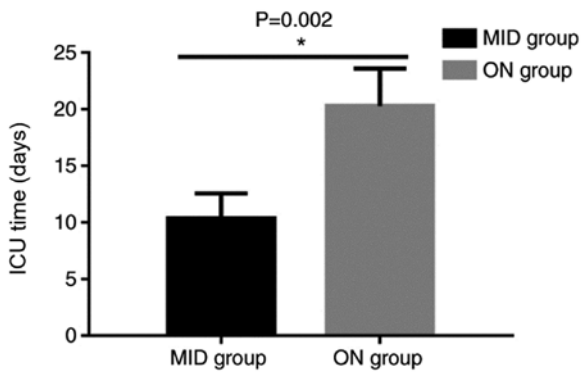


Figure 1. Duration of stay at the ICU compared between the MID and the ON group. * $P<0.05$. ICU, intensive care unit; ON, open necrosectomy; MID, minimally invasive drainage.

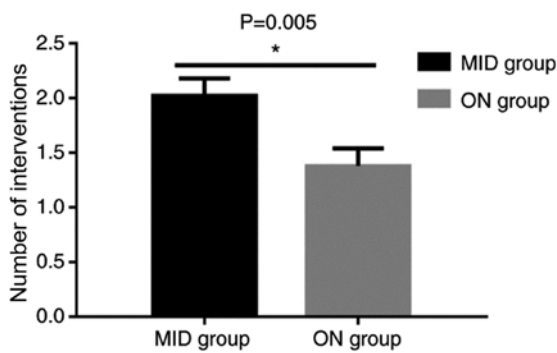


Figure 2. Number of interventions in the MID and the ON group. * $P<0.05$. ON, open necrosectomy; MID, minimally invasive drainage.

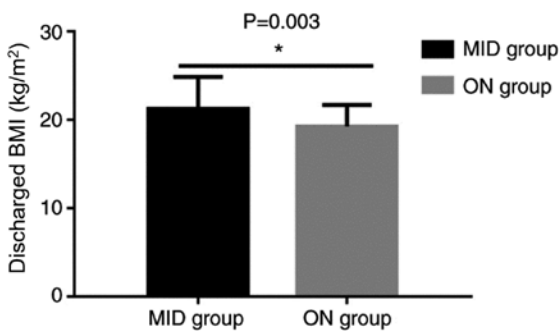


Figure 3. Comparison of BMI at discharge in the MID and the ON group. * $P<0.05$. ON, open necrosectomy; MID, minimally invasive drainage; BMI, body mass index.

not differ significantly between the MID and ON groups. Specifically, the incidence of diarrhea (12/61 vs. 4/40), abdominal pain (6/61 vs. 3/40), abdominal distention (6/61 vs. 5/40), exogenous trypsin intake (19/61 vs. 10/40) and FE-1 concentration (264.03 ± 22.88 vs. 245.74 ± 30.68 $\mu\text{g/g}$) in the two groups was comparable (Table III). In addition, no statistically significant difference in endocrine pancreatic function (FBG, FINS, fasting C-peptide, HbA1c, 2-h PG, 2-h insulin and 2-h C-peptide) was observed between the two groups (Table IV).

As outlined in Table V and Fig. 4, the results of the assessment with the QoL questionnaire indicated significant

Table II. Clinical characteristics of the patients in the MID group and ON group during the follow-up time.

Variable	MID (n=61)	ON (n=40)	P-value
Physical activity level based on walking distance (km/day)			
<3	25	14	0.546
3-5	10	11	0.179
5-10	10	5	0.590
>10	3	4	0.430
None	13	6	0.604
BMI (kg/m ²)	21.25 ± 3.60	19.26 ± 2.42	0.003
Reduced oil diet			0.801
Present	50	32	
Absent	11	8	
Diabetes symptoms			1.000
Present	10	7	
Absent	51	33	
Insulin use			0.709
Present	4	4	
Absent	57	36	
Loss of pancreas ^a			<0.001
Present	17	28	
Absent	44	12	
Pseudocyst			0.673
Present	3	3	
Absent	58	37	
Intestinal fistula			0.430
Present	3	4	
Absent	58	36	

^aLoss of whole pancreas was determined by careful comparison of the CT images prior to and after the interventions. ON, open necrosectomy; MID, minimally invasive drainage. These clinical characteristics were determined at the end of the follow-up time.

differences between the two groups in terms of general health perception (19.39 ± 3.07 vs. 17.37 ± 3.63 , $P=0.003$; Fig. 4A), vitality (18.93 ± 2.88 vs. 17.57 ± 3.47 , $P=0.035$; Fig. 4B), social role functioning (8.85 ± 1.43 vs. 8.15 ± 1.98 , $P=0.042$; Fig. 4C), emotional role functioning (5.33 ± 1.07 vs. 4.82 ± 1.25 , $P=0.034$; Fig. 4D), mental health (24.21 ± 3.31 vs. 22.57 ± 3.91 , $P=0.026$; Fig. 4E) and total QoL score (125.12 ± 13.16 vs. 116.50 ± 16.94 , $P=0.005$; Fig. 4F). However, physical functioning (26.77 ± 3.29 vs. 25.75 ± 4.04 , $P=0.168$), physical role functioning (6.77 ± 1.67 vs. 6.20 ± 1.69 , $P=0.099$) and bodily pain (10.78 ± 1.46 vs. 10.60 ± 1.52 , $P=0.556$) did not differ significantly between the MID and ON groups.

Discussion

Several studies indicated that MID is the preferred method for the treatment of IPN. The present study demonstrated

Table III. Comparison of pancreatic exocrine function between patients in MID group and ON group.

Variable	MID (n=61)	ON (n=40)	P-value
Diarrhea			0.268
Present	12	4	
Absent	49	36	
Abdominal pain			1.000
Present	6	3	
Absent	55	37	
Abdominal distention			0.749
Present	6	5	
Absent	55	35	
FE-1 ($\mu\text{g/g}$)			0.968
<200	12	8	
\geq 200	49	32	
Mean	264.03 \pm 22.88	245.74 \pm 30.68	0.656
Exogenous trypsin intake			0.653
Present	19	10	
Absent	42	30	

ON, open necrosectomy; MID, minimally invasive drainage; FE-1, fecal elastase-1.

Table IV. Comparison of pancreatic endocrine function between patients in MID group and ON group.

Variable	MID (n=61)	ON (n=40)	P-value
FBG	5.95 \pm 1.44	6.91 \pm 2.85	0.055
HbA1c (%)	5.96 \pm 1.04	6.49 \pm 1.88	0.073
FINS	7.24 \pm 0.81	9.98 \pm 1.83	0.130
Fasting C-peptide	1.41 \pm 0.70	2.07 \pm 0.55	0.160
2-h insulin	34.03 \pm 3.32	43.40 \pm 7.25	0.194
2-h C-reactive peptide	5.21 \pm 0.38	5.33 \pm 0.53	0.859
2-h PG	11.54 \pm 8.09	11.98 \pm 6.61	0.777

ON, open necrosectomy; MID, minimally invasive drainage; FBG, fasting blood glucose; HbA1c, glycated hemoglobin; FINS, free insulin; PG, plasma glucose.

that the patients in the MID group had a higher BMI at the follow-up than those in the ON group, while no significant difference was present prior to the intervention. This result indicates that MID is able to affect metabolism and nutrition. ON thoroughly removes necrotic tissue but may lead to loss of pancreatic tissue. The time spent at the ICU by patients subjected to ON was longer than that of patients who received MID ($P<0.05$). However, it cannot be determined whether MID is directly able to reduce the time at the ICU, since the patients treated with ON had typically more severe IPN or organ failure, requiring treatment for a longer duration. Furthermore, patients subjected to MID required an

Table V. Comparison of QoL between patients in the MID group and ON group.

Item	MID (n=61)	ON (n=40)	P-value
Physical functioning	26.77 \pm 3.29	25.75 \pm 4.04	0.168
Physical role functioning	6.77 \pm 1.67	6.20 \pm 1.69	0.099
Bodily pain	10.78 \pm 1.46	10.60 \pm 1.52	0.556
General health perception	19.39 \pm 3.07	17.37 \pm 3.63	0.003
Vitality	18.93 \pm 2.88	17.57 \pm 3.47	0.035
Social role functioning	8.85 \pm 1.43	8.15 \pm 1.98	0.042
Emotional role functioning	5.33 \pm 1.07	4.82 \pm 1.25	0.034
Mental health	24.21 \pm 3.31	22.57 \pm 3.91	0.026
Total QoL score	125.12 \pm 13.16	116.50 \pm 16.94	0.005

ON, open necrosectomy; MID, minimally invasive drainage; QoL, quality of life.

increased frequency of MID procedures than the patients in the ON group. Patients with AP may develop prediabetes and/or DM after being discharged from hospital (24). Impairment of the endocrine function of the pancreas after AP is associated with a decreased level of plasma insulin after fasting glucose stimulus and it occurs more frequently in patients recovering from severe AP (SAP) (25). The pancreas is a key organ in glucose homeostasis and the development of DM as a result of pancreatic necrosis after AP has been reported (26). Although numerous studies demonstrated that AP, and SAP in particular, may impair pancreatic endocrine function (12), there was no significant difference in this function between the MID and ON groups of the present study. As documented in a previous study by our group, the extent of pancreatic necrosis, wall of necrosis and insulin resistance are independent risk factors for new-onset DM after AP (27), and this risk is increased in patients with simultaneous pancreatic necrosis and persistent organ failure (28). Thus, pancreatic necrosis may have a critical role in the impairment of pancreatic endocrine function. The interventional methods to remove the necrotic tissue have a limited effect on diabetes after AP. There was also no significant difference in the exocrine function of the pancreas between the MID and ON groups of patients.

Several studies verified the validity and reliability of the SF-36 questionnaire for the evaluation of QoL (29-35). The physical functioning aspect of the QoL questionnaire was improved during the first year of recovery from the acute necrotizing pancreatitis (36). The total QoL score among patients with SAP after five years was comparable to that of the normal population (37). Numerous complications after IPN, including incisional hernia, gastrointestinal fistulas, intra-abdominal bleeding and diabetes, affected the QoL. Certain patients in the MID group required repeated acupuncture and placement of multiple drainage tubes, which may make them feel less comfortable than patients undergoing ON. The present study did not identify any

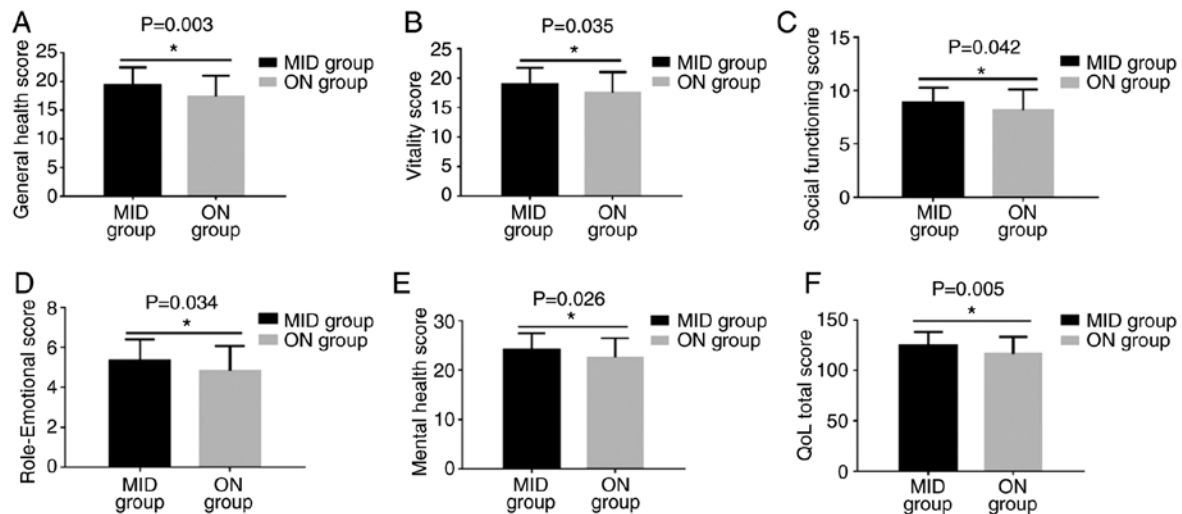


Figure 4. Results of the Short Form 36-item questionnaire for QoL compared between the two groups. (A) General health score, (B) vitality score, (C) social functioning score, (D) role-emotional score, (E) mental health score, (F) QoL total score. * $P < 0.05$. ON, open necrosectomy; MID, minimally invasive drainage; QoL, quality of life.

significant differences in physical functioning, physical role functioning and bodily pain between the two groups. However, MID provided a significant benefit over ON in terms of general health, vitality, social functioning, emotional role functioning and mental health. It is worth mentioning that it is not possible to exclude the possibility that these differences are derived from a difference in initial disease severity between groups. These results indicate that although MID and ON have a similar impact on physical indices, they have a different impact on mental and social indices. This is probably due to the fact that patients that underwent MID had a better QoL post-surgery. MID resulted in better general health, vitality and mental health as compared with ON. The reason for this difference may be the fact that patients treated with ON suffered from the abdominal incision, reduced BMI and severe pancreatic complications. These complications obviously affected their mental and social functioning. Accordingly, patients in the MID group had higher total QoL scores than patients undergoing ON.

The major limitation of the present study is its retrospective design. A prospective randomized controlled study will be necessary to determine the advantages and disadvantages of ON and MID for patients with IPN. Another limitation is that the sample size of the present study is relatively small. Future studies including a larger number of patients are required. Furthermore, the present study was a single-center study. A multi-center study or a meta-analysis including data from more centers will provide more convincing conclusions in the future.

In conclusion, the present study demonstrated that patients with IPN who received MID achieved a better QoL than those treated with ON. However, the endocrine and exocrine functions of the pancreas were similar in the two groups.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

JT, JL, QX, and JZ designed the study. YY, QX, LK, ZT and WL collected the data and performed statistical analysis. QX, WL and JT wrote the manuscript. All authors read and reviewed the final version of the manuscript.

Ethics approval and consent to participate

The experimental protocol was approved by the Ethics Committee of the Jinling Hospital (Nanjing, China). Written informed consent was obtained from all patients.

Patient consent for publication

Written informed consent regarding the publication of clinical data was obtained from every patient enrolled in this study.

Competing interests

The authors declare that they have no competing interests.

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