

# Factors Associated with the Success Rate of Endoscopic Retrograde Cholangiopancreatography with Standard Technique followed by Laparoscopic Cholecystectomy in the Management of Choledocholithiasis: A Single-Center Experience

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## Abstract

**Background** Choledocholithiasis is the most common benign biliary disease. Endoscopic retrograde cholangiopancreatography (ERCP) followed by laparoscopic cholecystectomy (LC) has been the first-line therapy in recent years, although laparoscopic common bile duct exploration has promising results. This retrospective study aimed to define the factors associated with biliary clearance by standard ERCP technique and conversion rate of LC.

**Materials and Methods** We retrospectively evaluated the records of 217 choledocholithiasis patients who had undergone ERCP with stone removal by the standard technique from 2010 to 2018. A failed ERCP was defined when the first ERCP session could not remove the stones. The number of patients who later underwent open cholecystectomy or LC was also recorded. Conversion was defined when LC had to be converted OC.

**Statistical Analysis** Student's *t*-test was used for the comparison of continuous variables. Nominal variables were analyzed using Pearson's chi-square test or Fisher's exact test. Binary logistic regression was performed for multivariate analysis.

**Results** The rate of successful biliary clearance was 81.1%. Of the patients, 109 (50.2%) had difficult stones. Increasing age ( $p = 0.004$ ), increasing number ( $p = 0.001$ ), and increasing size of stone ( $p < 0.001$ ) were the three significant factors that were associated with the failure of biliary clearance. The difficult stone group had a higher failure rate of ERCP and a higher conversion rate of LC compared with the easy stone group ( $p = 0.001$  and  $p = 0.027$ , respectively).

**Conclusions** ERCP with the standard technique is a highly effective and safe management option for patients with common bile duct (CBD) stones. The difficult stone group was found to be an independent risk factor that affected the success rate of both ERCP and the following LC. Difficult stone criteria should be assessed to identify a patient who might benefit from laparoscopic CBD exploration.

## Keywords

- CBD stones
- ERCP
- choledocholithiasis
- standard technique
- difficult stones
- endoscopic retrograde cholangiopancreatography
- laparoscopic cholecystectomy
- conversion

## Introduction

Choledocholithiasis, the presence of stones in the common bile duct (CBD), is the most common benign biliary disease, and is found in 10% to 15% of the population. The condition occurs more frequently in patients with advanced ages.<sup>1</sup> The majority of choledocholithiasis come from the migration of stone from the gallbladder into the CBD. However, 10 to 18% of patients who have previously undergone cholecystectomy also can present with CBD stones after surgery.<sup>2</sup> For a patient with choledocholithiasis, early treatment is needed to reduce the risk of fatal complications such as severe pancreatitis and severe cholangitis.<sup>3</sup>

There are many options to treat choledocholithiasis, such as CBD exploration either by open- or minimally-invasive approaches or endoscopy intervention. However, the development of stone extraction techniques in recent years has enabled endoscopic retrograde cholangiopancreatography (ERCP) to be the first-line therapy. Stone extraction with ERCP has high success rates and low complication rates. However, failure of treatment occasionally occurs in the following setting: (1) stone diameter is greater than 1.5 cm, (2) there are more than three stones, (3) there is impaction of the stone(s), (4) a perampullary diverticula is present, or (5) there is a narrowing of the bile duct distal to the stone.

Sphincterotomy and stone removal by balloon or dormia basket, with or without a mechanical lithotripter, is considered to be the standard technique. When the standard approach fails, additional interventional techniques such as electrohydraulic/laser lithotripsy or extracorporeal shock-wave lithotripsy can be used. However, those options are only available in limited centers.<sup>4,5</sup>

Biliary decompression with plastic endobiliary stent would be an alternative approach if another advanced option were unavailable. However, this method requires one or more repeated ERCP sessions to achieve success.<sup>6</sup> Better understanding of the factors associated with successful complete biliary clearance would help endoscopists to predict the chance of success and to prepare the additional instruments before starting the procedure.

The primary aim of this study was to investigate the factors that are associated with the success rate of biliary clearance of ERCP with standard technique followed by laparoscopic cholecystectomy (LC) in patients with CBD stone. The secondary aim was to identify the characteristic of patients with difficult stones.

## Materials and Methods

### Ethics

The project was approved by the Khon Kaen University Ethics Committee for Human Research (registration number: HE601264).

### Study Population

From 2010 to 2018, there were 217 patients with CBD stones who underwent therapeutic ERCP at the Surgical Endoscopy

Unit, Srinagarind Hospital, Khon Kaen University. Patients age younger than 18 years or older than 80 years were excluded. The diagnosis of choledocholithiasis was established in the presence of clinical symptoms and the detection of bile duct stone(s) on computed tomography (CT) or magnetic resonance cholangiopancreatography (MRCP).

### Procedure

All procedures were performed by seven endoscopists using a standard endoscope (Olympus TGF-145 or FujiFilm ED-580XT); five endoscopists had more than 5 years of experience, whereas two endoscopists had less than 5 years of experience. The written informed consent was obtained from every patient before the procedure. The patients were anesthetized under conscious sedation technique with midazolam or propofol without orotracheal intubation. For duodenal relaxation, butylscopolamine was administered. In case the patient's condition was not appropriate, standard general anesthesia would, instead, be used.

We used 10% lidocaine spray for pharyngeal anesthesia. Intravenous antibiotics were given before the start of the procedure. Patients were in the prone position during the procedure. Endoscopic sphincterotomy was performed after deep cannulation of the bile duct with a papillotome. In case of any stricture of bile duct distal to the stone, balloon dilatation with a 6- or 8-mm balloon was performed. If transpapillary dilatation was needed, sphincteroplasty with a 10-, 12-, or 15-mm balloon was performed. Standard techniques were implemented for the removal of stones, with a balloon catheter, a four-wire basket catheter, or both as a tool. Mechanical lithotripsy or endobiliary stent placement was executed in a difficult case. If complete stone removal was not possible in the first session, the patient would be scheduled for surgery or sequential ERCP procedures within 2 to 3 months. To prevent post-ERCP pancreatitis, we used prophylactic pancreatic duct stent and/or indomethacin suppositories in the patient who had difficult biliary cannulation.

### Data Collection

The following data were collected from the electronic medical records: age, sex, clinical presentation, physical examination, clinical diagnosis, blood tests, imaging- and endoscopic findings, endoscopic technique used, and short-term outcomes.

Difficult stone was defined by the presence of any of the following: stone diameter larger than 1.5 cm, more than three stones, presence of perampullary diverticula, and narrowing of the biliary duct distal to the stone.

Post-ERCP complications were assessed and recorded using the definition from the 1991 consensus guidelines.<sup>7</sup> Post-ERCP pancreatitis was defined as the new onset of abdominal pain with an elevation of serum amylase more than three times and persistent for more than 24 hours after the procedure. Hemorrhage was defined as clinical evidence of bleeding with a decrease of hematocrit of more than 6%. Cholangitis was defined as an elevation in body temperature more than 38°C, presumably from the biliary cause.

Perforation was diagnosed based on the detection of air or bile leakage by the cross-sectional imaging modality.

The number of patients who later underwent open cholecystectomy (OC) or LC was also recorded. A conversion was defined as an incidence when LC had to be converted to OC.

### Statistical Analysis

Statistical analysis was performed using STATA software version 10 (StataCorp., College Station, Texas, United States). Continuous variables were expressed as means and standard deviation. Continuous variables were compared using Student's *t*-test. Categorical variables were expressed as number and percentage and were analyzed using Pearson's chi-square test or Fisher's exact test. Factors with *p*-values under 0.25 were included in the multivariate analysis using binary logistic regression. Results with *p*-values of less than 0.05 were considered to be statistically significant.

### Results

We enrolled a total of 217 patients in this study. The overall mean age was  $60.6 \pm 14$  years old, and 105 (48.4%) of the patients were male. The majority (62.7%) presented with cholangitis. The other presenting symptoms include abdominal pain, pancreatitis, and jaundice. The CBD stones were incidentally detected in eight patients. Regarding the number of stones, 118 (56.5%) patients had single stones, whereas 91 (43.5%) had multiple stones. The mean number and size of the stones were  $1.47 \pm 1.03$  stones and  $9.78 \pm 4.63$  mm, respectively. The mean size of the CBD was  $11.52 \pm 5.13$  mm. Thirty-five (16.1%) patients had undergone prior cholecystectomy. Of all the patients, 118 (54.4%) had at least one comorbidity, with hypertension being the most common comorbidity. Duodenal diverticulum was the most commonly found variation (► **Table 1**).

By using the standard technique, the success rate of biliary clearance in the first ERCP session was 81.1% ( $n = 176$ ). The success rate of ampullary cannulation was 94.0% ( $n = 204$ ). Endoscopic sphincterotomy was performed in 142 (69.6%) patients, and endoscopic sphincterotomy with additional endoscopic balloon dilatation was performed in 62 (30.4%) patients. Additional mechanical lithotripsy was adopted in three (1.5%) patients. The stones were removed by balloon extraction in 200 (98.6%) patients. Plastic stent placement was inserted in 49 (22.6%) patients who were suspected of having impacted stone, residual stone, large stone, bile duct stricture, bile duct tumor, and clinical sepsis.

When the patients were divided into two groups based on the success of biliary clearance, there was no significant difference in terms of gender, body mass index, clinical presentation, initial serum alkaline phosphatase, and total serum bilirubin. However, the differences were significant between the patients of the two groups in terms of the age, initial serum alanine aminotransferase (ALT), initial serum aspartate aminotransferase (AST), prior cholecystectomy, the existence of duodenal diverticulum, number of stones, size

**Table 1** Demographic data of patients who underwent ERCP with the standard technique

Variables	Results
Age	$60.6 \pm 14$
Gender, male/female	105 (48.4%)/112 (51.6%)
Clinical presentation	
Cholangitis	136 (62.7%)
Pancreatitis	10 (4.6%)
Abdominal pain	57 (26.3%)
Jaundice	6 (2.8%)
Incidental findings	8 (3.7%)
Single stone/multiple stones	91 (43.5%)
Number of stone (stone)	$1.47 \pm 1.03$
Size of stone (mm)	$9.78 \pm 4.63$
Size of bile duct (mm)	$11.52 \pm 5.13$
History of cholecystectomy	35 (16.1%)
Comorbidity	118 (54.4%)
Hypertension	73 (33.6%)
Diabetes mellitus	48 (22.1%)
Heart disease	13 (6.0%)
Liver disease	9 (4.1%)
Chronic kidney disease	8 (3.7%)
Pulmonary disease	6 (2.7%)
Anatomical variation	
Duodenal diverticula	44 (20.3%)
Duodenal polyp	4 (1.8%)
Bile duct stricture	13 (6.0%)
Conversion from laparoscopic cholecystectomy to open cholecystectomy	4 (3.1%)

Abbreviation: ERCP, endoscopic retrograde cholangiopancreatography.

of stone, mean size of CBD, and the identification of difficult stones (► **Table 2**).

According to the multivariate analysis with binary logistic regression, the only three independent risk factors affecting the outcome of the ERCP were the patient's age, number of stones, and size of the stone (► **Table 3**).

### Difficult Stones

Of the 217 patients, 109 (50.2%) had difficult stones. There were no significant differences between the difficult group and the easy stone group in terms of age, laboratory parameters, and clinical presentation. Nevertheless, the percentage of male patients with difficult stones was significantly higher than the percentage of their female counterparts ( $p = 0.025$ ). The success rate of biliary clearance in the first ERCP session was significantly higher in the easy stone group ( $p = 0.001$ ). The overall complication occurred more frequently in the difficult stone group. However, the difference was not statistically significant (► **Table 4**).

**Table 2** Main difference between patients with success and failure in first ERCP sessions

Variables	Success (n = 176)	Unsuccessful (n = 41)	p-Value
Age	59.09 ± 14.32	67.32 ± 12.96	<0.001
Gender, male/female	85 (48.29%)	21 (51.21%)	0.736
BMI (kg/m <sup>2</sup> )	23.27 ± 3.90	22.45 ± 3.78	0.226
Clinical presentation			
Cholangitis	109 (61.93%)	27 (65.85%)	0.640
Pancreatitis	7 (3.98%)	3 (7.32%)	0.359
Abdominal pain	50 (28.41%)	6 (14.63%)	0.070
Jaundice	4 (2.27%)	2 (4.88%)	0.360
Incidental findings	6 (3.41%)	2 (4.88%)	0.653
Laboratory findings			
ALT	79.92 ± 92.24	44.27 ± 54.21	0.018
AST	80.80 ± 84.40	50.02 ± 65.88	0.030
ALP	215.60 ± 167.62	183.98 ± 202.96	0.298
Total bilirubin	3.02 ± 5.36	2.63 ± 5.90	0.681
Jaundice (TB > 2.5)	50 (28.41%)	6 (14.63%)	0.069
Endoscopic findings			
Normal	114 (64.77%)	20 (48.78%)	0.05
Diverticulum	29 (16.48%)	15 (36.58%)	0.004
Previous sphincterotomy	11 (6.25%)	2 (4.87%)	0.739
Duodenal polyp	4 (2.27%)	0 (0%)	0.331
CDD	0 (0%)	1 (2.44%)	0.038
Bulging ampulla	1 (0.57%)	0 (0%)	0.629
CBD stricture	12 (6.82%)	1 (2.43%)	0.288
Others	5 (2.84%)	2 (4.89%)	
Previous cholecystectomy	22 (14.28%)	11 (36.67%)	0.021
Number of stones	1.30 ± 0.69	2.40 ± 1.83	<0.001
Single stone proportion	107 (63.69%)	11 (26.83%)	<0.001
Mean maximum size of stone (mm)	8.78 ± 3.93	13.69 ± 5.10	<0.001
Big stone > 15 mm	43 (24.43%)	21 (51.22%)	<0.001
Mean size of bile duct (mm)	10.48 ± 3.88	15.63 ± 7.12	<0.001
Difficult stone	79 (44.88%)	30 (73.17%)	0.001
LOS (days)	10.12 ± 3.88	5.08 ± 11.53	<0.001

Abbreviations: ALP, alkaline phosphatase; ALT, alanine transaminase; AST, aspartate transaminase; BMI, body mass index; CBD, common bile duct; CDD, choledochoduodenostomy; ERCP, endoscopic retrograde cholangiopancreatography; LOS, length of stay; TB, total bilirubin.

**Table 3** Multivariate analysis for factors affecting endoscopic success

Variables	Odds ratio	95% confidence interval	p-Value
Age	0.920	0.869–0.974	0.004
Abdominal pain	3.483	0.735–16.509	0.116
Number of stone	0.408	0.235–0.709	0.001
Size of stone	0.820	0.736–0.913	<0.001
Diverticulum	0.997	0.248–4.012	0.997

## Complications

There were post-ERCP complications in 30 (13.8%) patients. Pancreatitis was the most common complication followed

by cholangitis. There were three (1.38%) cases of post-ERCP mortality. The overall length of hospital stay was 6.0 ± 6.4 days (► **Table 4**).

**Table 4** Characteristic and outcome difference between patients in the easy and difficult stone groups

Variables	Easy stone (n = 108)	Difficult stone (n = 109)	p-Value
Age	58.76 ± 14.53	62.50 ± 14.11	0.055
Gender (male/female), n (%)	61 (56.48%)/47 (43.52%)	45 (41.28%)/64 (58.72%)	0.025
BMI (kg/m <sup>2</sup> )	23.40 ± 4.07	22.84 ± 3.69	0.296
Lab			
ALT	74.19 ± 85.49	72.19 ± 89.58	0.866
AST	71.48 ± 74.49	78.47 ± 89.01	0.531
ALP	192.79 ± 142.01	226.30 ± 201.36	0.158
Total bilirubin	3.26 ± 6.35	2.64 ± 4.40	0.408
Jaundice (TB > 2.5)	30 (27.78%)/78 (72.22%)	26 (23.85%)/83 (76.15%)	0.509
Presentation			
Cholangitis	67 (62.03%)	69 (63.30%)	0.847
Pancreatitis	7 (6.48%)	3 (2.75%)	0.191
Abdominal pain	31 (28.70%)	25 (22.94%)	0.333
Jaundice	1 (0.93%)	5 (4.59%)	0.100
Incidental findings	2 (1.85%)	6 (5.50%)	0.154
Success rate	97 (89.81%)	79 (72.47%)	0.001
LOS (days)	5.46 ± 4.34	6.60 ± 7.88	0.191
Complication	12 (11.11%)	18 (16.51%)	0.249
Post-ERCP pancreatitis	6 (5.56%)	8 (7.34%)	0.593
Cholangitis	5 (4.63%)	5 (4.59%)	0.988
Perforation	0 (0.00%)	1 (0.92%)	1.000
Hemorrhage	1 (0.92%)	2 (1.83%)	1.000
Multiorgan failure	1 (0.92%)	3 (2.75%)	0.622
30-d mortality	1 (0.92%)	2 (1.83%)	1.000
Conversion from laparoscopic cholecystectomy to open cholecystectomy	0.00% (N = 77)	7.41% (N = 54)	0.027

Abbreviations: ALP, alkaline phosphatase; ALT, alanine transaminase; AST, aspartate transaminase; BMI, body mass index; ERCP, endoscopic retrograde cholangiopancreatography; LOS, length of stay; TB, total bilirubin.

### Following Cholecystectomy

A total of 137 patients underwent cholecystectomy in our hospital, whereas the rest had previous cholecystectomy or refused additional cholecystectomy in our hospital. There were 131 patients who underwent LC, but 4 (3.1%) of them had to be converted to OC due to severe adhesion or unstopable bleeding. The conversion group had a significantly older age and proportion of difficult stones than the unconverted group ( $p = 0.003$  and  $p = 0.027$ , respectively) (►Table 5).

### Discussion

Nowadays, ERCP and laparoscopic CBD exploration (LCBDE) have become the two most popular methods in the management of choledocholithiasis. In a previous meta-analysis, both procedures show promising results without significant differences in mortality, morbidity, retained stones, and failure rate.<sup>8</sup> LCBDE is a single-stage management, whereas ERCP followed by LC is a two-stage management. Although LCBDE has better results in regard to the lower costs and shorter hospital stays, many are hesitant to perform the procedure due

to insufficient training and a great incidence of biliary leakage.<sup>9,10</sup> On the other hand, the improvement of endoscopic technique such as mechanical lithotripsy, laser lithotripsy, and cholangioscopy made ERCP the popular choice.<sup>11-16</sup>

ERCP with standard stone removal technique is the simplest procedure in endoscopy that most of the hospital can perform, whereas laser lithotripsy is available only in some tertiary centers especially in a low- or middle-income country.<sup>17-19</sup> It would be beneficial to the treatment planning if the success or failure of ERCP with the standard stone removal can be predicted, and a patient with a higher risk of OC conversion can be identified.

In our study, 81.1% of patients with CBD stones were successfully treated with the standard technique in the first ERCP session, which was lower than the common range (87–100%).<sup>20,21</sup> However, half of the patients in our population were in the difficult stone group, which was significantly higher than the 15% rate reported in previous literature.<sup>4,5,22</sup> The success rate of ampullary cannulation was 94%, which was comparable with the previous literature.<sup>23</sup> The success rate of clearance was 86.3%, with successfully ampullary cannulation.



**Table 5** Following laparoscopic cholecystectomy after ERCP

	Laparoscopic cholecystectomy (N = 127)	Converted to open cholecystectomy (N = 4)	p-Value
Age	57.31 ± 14.51	76.25 ± 1.50	0.003
Gender, male/female	58 (45.67%)/69 (54.33%)	4 (100.00%)/0 (0.00%)	0.048
Body mass index (kg/m <sup>2</sup> )	23.28 ± 4.10	21.54 ± 3.23	0.396
Clinical presentation			
Cholangitis	71 (55.90%)	3 (75.00%)	0.632
Pancreatitis	5 (3.94%)	1 (25.00%)	0.173
Abdominal pain	44 (34.65%)	0 (0.00%)	0.300
Jaundice	3 (2.36%)	0 (0.00%)	1.000
Incidental finding	4 (3.15%)	0 (0.00%)	1.000
Overall complication	14 (11.02%)	0 (0.00%)	1.000
Pancreatitis	11 (8.66%)	0 (0.00%)	1.000
Cholangitis	3 (2.36%)	0 (0.00%)	1.000
Difficult stone	50 (39.37%)	4 (100.00%)	0.027

Abbreviation: ERCP, endoscopic retrograde cholangiopancreatography.

We analyzed the data to find the factors contributing to the success rate of biliary clearance. Univariate analysis found a significant relationship between the treatment outcome and the following factors: the patient's age, initial serum ALT, initial serum AST, duodenal diverticulum, and number and size of stones. However, only three independent factors, namely age, number of stones, and size of stones, were significantly related to the outcomes of biliary clearance in multivariate analysis. Younger patients in our study had a higher rate of success than older patients, which was similar to the previous study.<sup>4</sup> The results of increasing number and size of stones were also significantly correlated with a lower rate of success similar to the previous literature.<sup>4,5</sup>

There is no consensus regarding definition of difficult stone. In the American Society for Gastrointestinal Endoscopy guideline, clinical situations associated with difficult bile duct stone extraction were (1) stone larger than 15 mm, (2) stone that cannot be captured in the basket or mechanical lithotripsy, (3) stone with complex biliary stricture, (4) stone in patients with altered upper gut anatomy, and (5) Mirizzi's syndrome.<sup>15</sup> However, Ödemiş et al defined difficult stones as the stones that cannot be extracted in the first ERCP procedure using the standard technique; this was similar to the term for the successful procedure, not for a difficult stone, in our study.<sup>4</sup>

We divided patients into an easy group and a difficult stone group according to the criteria proposed in a previous study.<sup>5,22</sup> We, however, decided to exclude the impaction of stone from the criteria because we could not predict that before starting the procedure. The proportion of female patients in the difficult-stone group was significantly higher than their male counterparts. The success rate of biliary clearance was significantly lower in patients with difficult stones. Thus, by identifying a patient with difficult stone, the endoscopist can prepare the team for the potential advance procedure and provide appropriate tools such as mechanical lithotripsy, laser lithotripsy, or extracorporeal shockwave

lithotripsy before the start of ERCP to increase the chance of complete biliary clearance rate, similar to that reported in previous literature.<sup>24-28</sup>

We found a higher rate of complication in post-ERCP pancreatitis and cholangitis compared with 3.5% and 1.4%, respectively, in the previous literature.<sup>29</sup> We also found a similar rate of post-ERCP bleeding and ERCP-related perforation compared with previous literature.<sup>29</sup> Our three patients who had post-ERCP mortality were all caused by severe cholangitis leading to multiorgan failure. The information on the risk factors of pancreatitis and cholangitis, such as sphincter of Oddi dysfunction, pancreatic intervention, and inadequate cleansing of the lumen during duodenoscopy, which were described in the previous studies,<sup>29,30</sup> could not be accessed in our retrospective study.

The overall complication rate was 13.8%, which was higher than that reported in the previous literature. To be specific, the rates of post-ERCP pancreatitis and post-ERCP cholangitis were higher,<sup>29</sup> whereas the rates of ERCP-related hemorrhage and perforation were comparable with previous studies. Our mortality rate (1.4%) was also higher than that previously reported. All three patients who were admitted to the hospital due to cholangitis were dead from multiorgan failure despite emergency ERCP with biliary drainage being performed. This difference in both the complication rate and the mortality rate between this study and the previous literature might be explained by a larger proportion of difficult stones in our study and the mixture of elective and emergency cases in our study population.<sup>29,30</sup>

Two-stage preoperative ERCP with stone removal followed by LC was the treatment of choice in our hospital. Our conversion rate was lower than that in the previous literature.<sup>31</sup> Male gender, older age (>50 years), obese patients (body mass index > 30 kg/m<sup>2</sup>), and case performed by low-volume surgeons had a higher likelihood to conversion in overall LC.<sup>31-33</sup> However, there was no single factor related to preoperative ERCP that would make LC more difficult except the number

of ERCPs.<sup>34,35</sup> In our study, we found a higher age of patient and a larger proportion of difficult stone in the conversion group with statistical significance.

## Limitation

The main limitation of our study was its retrospective nature and a small incidence of the conversion. A larger prospective study would be indispensable to further assess the relationship between the risk factors and the outcomes of biliary clearance by the ERCP followed by LC.

## Conclusion

ERCP with the standard technique followed by LC is a highly effective and safe procedure in the management of CBD stones. Difficult stone group was found to be an independent risk factor affecting the success rate of ERCP with standard technique followed by LC. Before the start of the ERCP procedure, difficult stone criteria should be applied to evaluate the difficulty and identify a patient who might benefit from ERCP followed by LC or LCBDE, boosting the success rate of biliary clearance.

### Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this paper.

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