ADVERSE OUTCOMES OF ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY AT GASTROENTEROLOGY & HEPATOLOGY CENTERS IN SULAYMANIYAH AND DUHOK CITY

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ABSTRACT

Background

Endoscopic retrograde cholangiopancreatography (ERCP) has a significant and managing management of pancreaticobiliary diseases in Iraq and Kurdistan. Evaluating ERCP adverse outcomes is essential in raising the effectiveness and safety of ERCP.

Objectives

To review and measure the rate of ERCP complications in our centre and compare our results with other countries.

Patients and Methods

The present study was a prospective cross-sectional study carried out in the Kurdistan Center of Gastroenterology and Hepatology (KCGH) in Sulaimani city and Azadi Gastroenterology and Hepatology Center in Duhok city, Kurdistan region-Iraq through the period of one year from 1st of November 2020, to 31st of October, 2021 on a sample of two hundred patients underwent ERCP; 140 patients from Sulaimani city and 60 patients from Duhok city. The researcher followed up with the patients one month after completing ERCP through direct interviews or by phone calling to observe any ERCP adverse outcomes.

Results

The most typical indication for ERCP among studied patients was choledocholithiasis (43.7%), followed by; stent removal with occlusion cholangiography (12%) and biliary malignancy (11.6%). The commonest findings of ERCP among studied patients were bile duct dilation (42.3%), filling defects (33.8%) and bile duct strictures (14.7%). The post-ERCP complications were present in 45 (22.5%) patients, including pancreatitis (12.5%), cholangitis (4.5%), hypoxia (3.5%), bleeding (1.5%), perforation (1.5%) and death (0.5%).

Conclusion

The adverse outcomes of ERCP in KCGH in Sulaimani City and the Gastroenterology and Hepatology centre in Duhok city are increased in the last year..

Keywords: *Endoscopic Retrograde Cholangiopancreatography, Adverse outcomes.*

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INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is a common endoscopic technology used to diagnose and treat different pathologies of the biliary tree and pancreas [1-4]. ERCP functions have changed in the last three decades from diagnostic to therapeutic activities, especially after the development of endoscopic ultrasonography (EUS). The use of ERCP in treatment purposes for benign biliary diseases revealed higher efficacy and safety [5]. Shifting the ERCP from diagnostic to therapeutic is accompanied by a higher complexity of ERCP currently used for managing complex biliary and pancreatic disorders like biliary tract malignancies and chronic pancreatitis. The higher ERCP complexity requires highly experienced physicians to perform the procedure and to lower the risk of adverse outcomes of ERCP [6, 7].

The ERCP is accompanied by many adverse outcomes such as post-ERCP bleeding, perforation, pancreatitis, hypoxia, cholangitis, and rarely death. The incidence rates of these adverse outcomes depend on the ERCP procedure's complexity. The complexity is measured by different scores, like the grading system adopted by the American Society for Gastrointestinal Endoscopy (ASGE) [8]. The complexity of post-ERCP complications was graded into four levels (from 1 to 4) depending on severity and risk factors [8].

Post-ERCP pancreatitis is ERCP's most prevalent adverse outcome, recorded in about 3-10% of post-ERCP cases (9). Post-ERCP pancreatitis is accompanied by a high hospitalisation admission rate and death rate of (0.7%). These co-morbidities of pancreatitis following ERCP need preventive strategies reported by the European Society of Gastrointestinal Endoscopy (ESGE), like administration of non-steroidal anti-inflammatory agents (diclofenac or indomethacin) rectally immediately before or after ERCP unless contraindicated. The ESGE also recommended low cannulation attempts, restriction application of pancreatic guidewire as a backup for biliary cannulation, encouraging the use of needle-knife fistulotomy, and low endoscopic papillary balloon dilation [10]. Recently, some authors documented higher efficacy and safety of NSAIDs in preventing post-ERCP pancreatitis in high-risk patients 11, 12. Infection is a common complication of ERCP and a common cause of mortality related to ERCP. Post-ERCP-infection adverse outcomes commonly included cholecystitis, cholangitis, and liver abscess [10]. Bleeding is a highly frequent adverse outcome, specifically after endoscopic sphincterotomy, with incidence rates of 1-48% [13]. The post-ERCP bleeding ranged between self-limiting and life-threatening conditions, with a death rate of (0.3%). Most ERCP-bleeding conditions resolve spontaneously. However, some bleeding cases require blood transfusion and endoscopic intervention [13]. The perforation following ERCP is an uncommon adverse outcome. Still, it is a highly serious adverse event that needs early diagnosis and prompt management to lower the morbidity and mortality rates [14].

In Kurdistan, the ERCP is an effective and safe therapeutic and, to a lesser extent, a diagnostic method commonly for biliary stones, intra-biliary rupture of hydatid cyst, post-cholecystectomy complications, and rarely pancreatic pathologies in the last two decades [15, 16]. Although widespread use of ERCP in Iraqi and Kurdistan centres, there was a scarcity of kinds of literature discussing the adverse outcomes following ERCP. This study aimed to review and detect the rate of ERCP complications in our centre and compare our results with other countries.

METHODS

This study was a prospective cross-sectional study carried out in the Kurdistan centre of Gastroenterology and Hepatology (KCGH) in Sulaimani city and Azadi Gastroenterology and Hepatology centre in Duhok city, Kurdistan region-Iraq through the period of one year from 1st of November 2020, to 31st of October, 2021. Inclusion criteria were patients from all age groups scheduled to undergo ERCP who signed the written informed consent by the patient or first-degree relatives, known coagulopathy, ongoing acute pancreatitis, ongoing hypotension, including those with sepsis, cardiac insufficiency (NYHA class III, IV), respiratory insufficiency (pO2 < 60mmHg or requiring mechanical ventilation), active bulbar ulcer, and severely deformed bulb and patients refused to be enrolled in the study were the exclusion criteria. The study ethics were implemented regarding the Helsinki Declaration by documented agreement of patients, approved by the ethical committee in Kurdistan Board and hospital authority in addition to managing the adverse outcomes. A sample of two hundred patients who underwent ERCP was enrolled in the present study after eligibility to inclusion and exclusion criteria. One hundred and forty patients were recruited from KCGH in Sulaimani city, and sixty patients were recruited from Azadi Gastroenterology and Hepatology centre in Duhok city.

Patients' information was collected directly from patients, and the results of implemented ERCP and filled in a prepared questionnaire designed by researchers. The researchers followed up with the patients one month after completing ERCP through direct interviews or by phone calling to observe any ERCP adverse outcomes. The questionnaire included general characteristics of patients who underwent ERCP (age, gender, ethnicity, educational level, and residence), indications of ERCP, findings of ERCP, ERCP characteristics (endoscopic sphincterotomy, precut sphincterotomy), post-ERCP complications and post-ERCP complications types (pancreatitis and pancreatitis severity, bleeding, bleeding types and severity, perforation and perforation types, hypoxia, cholangitis, and cholangitis severity, and death).

Participants who visited or were referred to KCGH with Pancreaticobiliary diseases were indicated to undergo ERCP. We give the patients detailed informed consent verbally, and then written consent is given to be signed, which contains all the detail of the procedure; another paper is given to the patient to participate in this study. Demographic and detailed clinical and procedure-related data, which include an indication for ERCP, duration of the procedure, cannulation rate, therapeutic interventions performed, and ERCP-related morbidity and mortality, are collected based on a questionnaire we have already prepared. Before performing the ERCP, all patients (except those with active PUD or a history of upper GI bleeding) received an Indomethacin suppository. Both Gastroenterologists and Trainees do most procedures except for difficult procedures experienced. Gastroenterologists have performed. The procedure is performed under anaesthesia, and the sedative agents that are currently available for ERCP include midazolam, Propofol, and Pethidine. Using the PENTAX.EPK-i 5000 and OLYMPUS. EXERA CV-160 device. After ERCP, Patients will be observed in the recovery area for at least 2 hours after the procedure. Patients with new onset or worsening of upper abdominal pain or fever or evidence of bleeding developing during this observation period will be admitted to the hospital (or, for current inpatients, kept in the hospital).

The patients' data were entered and interpreted statistically by the SPSS program-26.

RESULTS

This study included two hundred patients who underwent Endoscopic retrograde cholangiopancreatography (ERCP) and presented with a mean age of (53.1 years) and a range of 4-85 years; 25% of patients were in the age group <40 years, 25.5% of them were in the age group 60-69 years, and 19% of them were in the age group of 70 years and more. Female patients more than males, with a female-to-male ratio of 1.7:1. The ethnicity of studied patients was Kurdish at 85.5% and Arabic at 14.5% of them. About half (47.5%) of patients who underwent ERCP were illiterate. The residence of patients who underwent ERCP was outside the city for 58.5% and inside the city for 41.5%. (Table 1)

The common indication for ERCP among studied patients was choledocholithiasis (43.7%), followed by; stent removal with occlusion cholangiography (12%), (Figure 1) .The common findings of ERCP among studied patients were bile duct dilation (42.3%), followed by filling defects (33.8%), (Figure 3).

Endoscopic sphincterotomy was done for 80.5% of patients during ERCP, and precut sphincterotomy was done for 14.5%. Biliary or pancreatic duct stenting was done commonly by plastic stents (67%), while stone extraction was implemented mainly by Extraction balloon (47.5%), and dilatation of bile duct stricture was done in 3.5%. Parasite extraction was implemented for 2.5% of studied patients (Table 2).

The post-ERCP complications were present in 45 (22.5%) patients who underwent ERCP, while 155 (77.5%) patients who underwent ERCP were not showing any complication. (Figure 3)

The most frequent post-ERCP complication was pancreatitis in 25 (12.5%) patients, which was distributed according to severity into; mild in 19 (9.5%) patients, moderate in 4 (2%) patients, and severe in 2 (1%) patients. The post-ERCP bleeding was present in 3 (1.5%) patients, two with immediate and one with delayed bleeding. The bleeding severity was mild for one patient, moderate for one patient, and severe for one patient. The perforation was also detected in 3 (1.5%) patients; one had type I perforation, one had type II perforation, and one had type IV perforation. The post-ERCP hypoxia was recorded in 7 (3.5%) patients. In comparison, post-ERCP cholangitis was shown in 9 (4.5%) patients, with one patient with mild cholangitis, four with moderate cholangitis, and four with severe cholangitis. The post-ERCP death was shown only for one patient with a mortality rate of in all studied patients of (0.5%). (Table 3)

Table 1. General characteristics of patients who underwent ERCP.

Variable	No.	%
Age mean±SD (53.1±18.7 years)		
<40	50	25.0
40-49	32	16.0
50-59	29	14.5
60-69	51	25.5
≥70	38	19.0
Gender		
Male	73	36.5
Female	127	63.5
Ethnicity		
Kurdish	171	85.5
Arabic	29	14.5
Educational level		
Illiterate	95	47.5
School	54	27.0
Undergraduate	20	10.0
Postgraduate	31	15.5
Residence		
Outside city	117	58.5
Inside city	83	41.5
Total	**200**	**100.0**

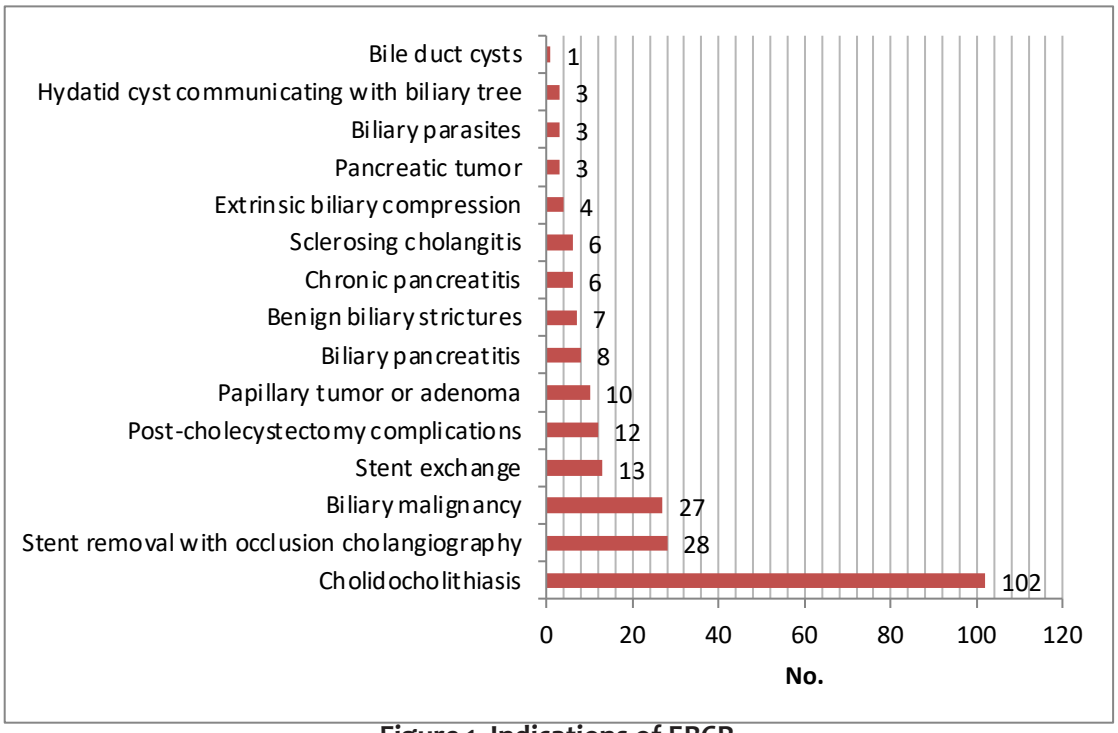

Figure 1. Indications of ERCP.

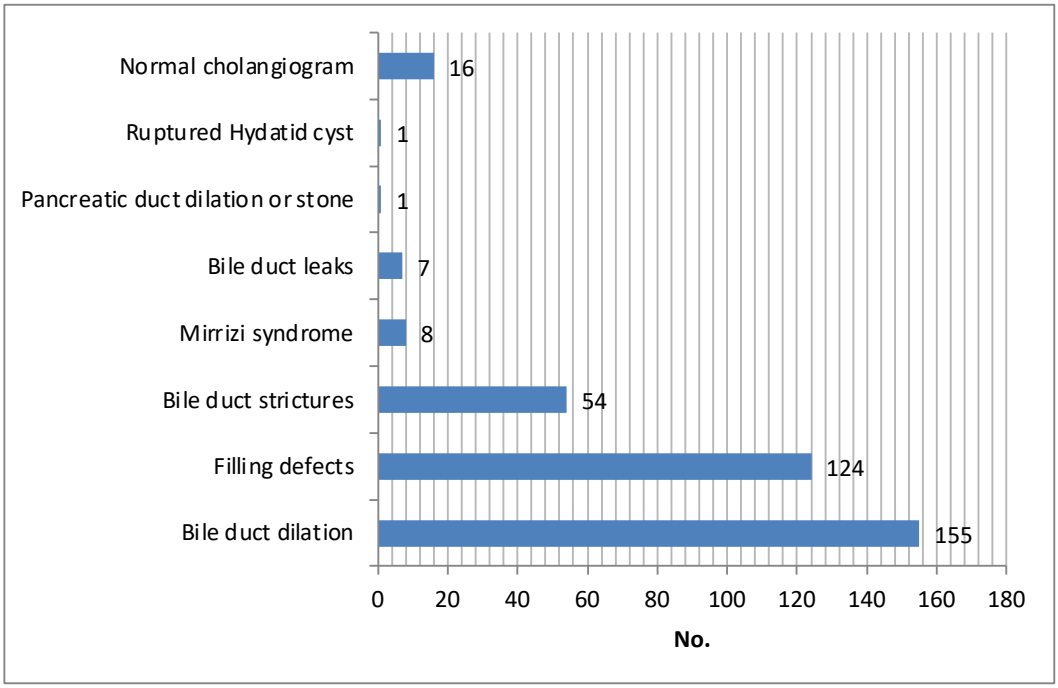

Figure 2. Findings of ERCP.

Table 2. ERCP characteristics.

Variable	No.	%
Endoscopic sphincterotomy		
Yes	161	80.5
No	39	19.5
Pre-cut sphincterotomy		
Yes	29	14.5
No	171	85.5
Biliary or pancreatic duct stenting		
No	47	23.5
Metallic	15	7.5
Plastic	134	67.0
Metallic and plastic	4	2.0
Stone extraction		
No	81	40.5
Basket	2	1.0
Balloon	95	47.5
Basket and balloon	22	11.0
Dilatation of bile duct stricture		
No	193	96.5
Balloon	4	2.0
Dilator	3	1.5
Parasite extraction		
Yes	5	2.5
No	195	97.5
Total	**200**	**100.0**

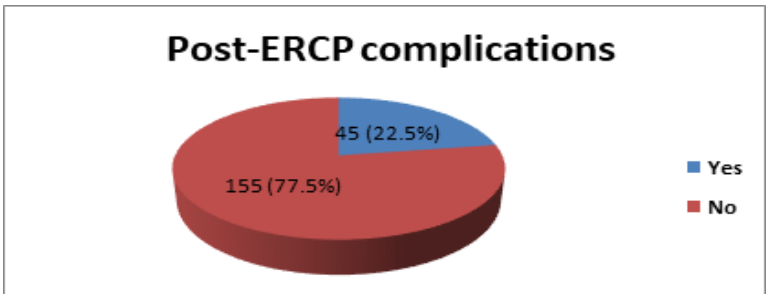

Figure 3. Post-ERCP complications.

Table 3. Post-ERCP complications types.

Variable	No.	%
Pancreatitis		
Yes	25	12.5
No	175	87.5
Pancreatitis severity		
Mild	19	9.5
Moderate	4	2.0
Severe	2	1.0
Bleeding		
Yes	3	1.5
No	197	98.5
Bleeding type		
Immediate post-ES bleeding	2	1.0
Delayed post-ES bleeding	1	0.5
Bleeding severity		
Mild	1	0.5
Moderate	1	0.5
Severe	1	0.5
Perforation		
Yes	3	1.5
No	197	98.5
Perforation severity		
Type I	1	0.5
Type II	1	0.5
Type IV	1	0.5
Hypoxia		
Yes	7	3.5
No	193	96.5
Cholangitis		
Yes	9	4.5
No	191	95.5
Cholangitis severity		
Mild	1	0.5
Moderate	4	2.0
Severe	4	2.0
Death		
Yes	1	0.5
No	199	99.5
Total	**200**	**100.0**

DISCUSSION

Since introducing the ERCP by McCune in 1968 [17], it has become the most common diagnostic and therapeutic method for diseases of the biliary tree and pancreas. With the widening of ERCP indications, there was an increased focus on the identification and prevention strategies for ERCP complications [18].

The present study showed that the mean age of patients who underwent ERCP was (53.1 years); 25% of them were in the age group 60-69 years, with a predominance of the female gender. These demographic characteristics are close to the results of Muslim et al. [21] retrospective observational study on 545 patients who underwent ERCP in the Gastroenterology and Hepatology Center in Al-Diwaniyah city (Central Iraq) reported that a higher proportion of studied patients were in the age group 60-69 years with prevalent female gender (60.36%). In the current study, 85.5% of included patients were Kurdish, and 14.5% were Arabic. This distribution is related to the displacement of the Arabic population to Kurdistan or the referral of patients from the other areas of Iraq. Our study showed that about half of the patients who underwent ERCP were illiterate. A prospective study conducted by Arslan and Cayci in Turkey found that the educational level and health literacy of patients who underwent ERCP affected the success of ERCP; they believe that improving health literacy would increase the success rates of diagnosis and treatment in patients who require ERCP [19].

The present study revealed that the commonest indication for ERCP among studied patients was choledocholithiasis (43.7%), followed by; stent removal with occlusion cholangiography (12%), and biliary malignancy (11.6%). These findings are close to the results of Alnajar et al. [20] retrospective case series study in Sulaimani City (Kurdistan region/Iraq) on records of 290 patients, which documented the most common indications for ERCP were choledocholithiasis (40.7%) and pancreaticobiliary tumours (33.8%). Our study revealed that common findings of ERCP among studied patients were bile duct dilation (42.3%), filling defects (33.8%), and bile duct strictures (14.7%). These findings agree with the results of many works of literature, such as Hormati et al. [21] cross-sectional study in Iran and Kröner et al. [22] study in the USA, which reported common findings of ERCP were the findings of choledocholithiasis like bile duct dilation or strictures. In our study, the endoscopic sphincterotomy was done for (80.5%) of patients during ERCP, and the biliary or pancreatic duct stenting was done commonly by plastic stents (67%). Stone extraction was implemented mainly by Extraction balloon (47.5%). These findings are close to the results of Tamura et. al [23] multi-centre retrospective cohort study on 362 patients who underwent ERCP, which stated that endoscopic sphincterotomy was an effective technique to prevent post-ERCP pancreatitis in patients with biliary neoplasms.

In the current study, post-ERCP complications were present in 45 (22.5%) patients who underwent ERCP. This post-ERCP complications rate is higher than the post-ERCP complications rate of (7.24%) recorded by Alnajar et al. [20] retrospective case series study in Sulaimani city. This high difference might be attributed to our study Gastroenterology and Hepatology centre is a tertiary training centre that received the more complicated cases from different Iraqi hospitals last year in addition to factors related to the experience of Physicians and the health status of patients received. However, our study's post-ERCP complications rate is lower than that of Chen et al. [24] study in China, which found that post-ERCP adverse events occurred in 31 (25.6%) patients. The ERCP is applied in high-volume and low-volume centres and by physicians of variable experiences in addition to the gradual training of physicians to acquire safe and effective ERCP [25]. Although these efforts, the post-ERCP adverse outcomes were shown in the rate of more than (10%) of patients in highly qualified centres [9].

The most frequent post-ERCP complication in the present study was pancreatitis in 25 (12.5%) patients. This complication is higher than the results of other studies. For example, Alizadeh et al. [26] study in Iran on 780 patients who underwent ERCP found that pancreatitis is the most common complication following ERCP at 3.6%. Our study showed that pancreatitis was mild in 19 (9.5%) patients, moderate in 4 (2%) patients, and severe in 2 (1%) patients. In the USA, a systematic review study by Kochar et al. [27] found that the incidence of pancreatitis following ERCP was (9.7%) with severity distribution; mild (8.6%), moderate (3.9%), and severe (0.8%). Our study showed that post-ERCP bleeding was present in 3 (1.5%) patients, two patients with immediate bleeding, and one patient with delayed bleeding, and the bleeding severity was distributed into mild, moderate, and severe in (0.5%, 0.5%, 0.5%, respectively). These findings are close to reports of the Yildirim study in Turkey, which

stated that the bleeding following ERCP occurred in one to two percent of patients who underwent ERCP with different intensities [28]. The current study found 3 (1.5%) patients were also detected post-ERCP perforation. This rate is higher than the results of the Koc et al. [29] study in Hong Kong, which reported a rate of (0.94%) for post-ERCP perforation. The post-ERCP perforation in the current study was classified into; type I, type II and type IV perforations (0.5%, 0.5%, and 0.5%, respectively). These findings are close to reports of Vezakis et al. [30] study in Greece, which documented that perforation is a rare post-ERCP complication that needs earlier diagnosis and management as it is a serious complication that is classified into four categories with different prognoses. In our study, post-ERCP hypoxia was recorded in 7 (3.5%) patients. Madani et al. [31] study in Iran reported hypoxia is a rare post-ERCP complication attributed to sedation and anaesthesia factors. Our study revealed post-ERCP cholangitis in 9 (4.5%) patients. This finding is close to the Peixoto et al. [32] study in Brazil, which found that post-ERCP cholangitis occurred in (4.9%) of patients. The mortality rate of ERCP in the present study was (0.5%). This mortality rate is lower than the ERCP hospital-based mortality rate of (3.7%) as reported by Sharma et al. [33] study in the USA. Variation in post-ERCP mortality rates is attributed to many factors related to post-ERCP complications and factors related to anaesthesia and hospital-based characteristics.

In conclusion, the adverse outcomes of endoscopic retrograde cholangiopancreatography in the Gastroenterology and Hepatology centre at Sulaimani city and Azadi Teaching Hospital are increased in the last few years. The common complications following ERCP are pancreatitis, cholangitis, hypoxia, bleeding, and perforation. The mortality rate related to ERCP complications is low.

Recommendations

This study recommended training physicians on ERCP under the supervision of highly qualified Specialists and strict adherence to preventive strategies for ERCP complications to lower the incidence of ERCP adverse outcomes. This study also recommended supporting further longitudinal large-sized studies on adverse events of ERCP.

Conflicts of interest

None

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