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Original Research Article

EVALUATION OF PATIENTS WITH POST-ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY PANCREATITIS

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ABSTRACT

Background: Endoscopic retrograde cholangiopancreatography (ERCP) is a widely used procedure for biliary and pancreatic disorders; however, post-ERCP pancreatitis (PEP) remains its most common complication. Early identification of patients at risk is crucial to reduce morbidity. Serum amylase and lipase measured early after ERCP and the neutrophil-lymphocyte ratio (NLR) have emerged as potential predictors of PEP. The study aimed to determine the incidence of PEP and evaluate early biochemical and inflammatory markers, along with associated complications.

Materials and Methods: The prospective observational study was conducted over one year at JN Medical College Hospital, Aligarh Muslim University, after ethical approval. A total of 150 adult patients undergoing ERCP were enrolled. Procedures were performed using standard techniques. Post-procedure monitoring included clinical assessment and measurement of serum amylase and lipase levels. Data were analysed using SPSS, with $p < 0.05$ considered statistically significant.

Results: Multiple cannulation attempts occurred in 63.1%, with a PEP rate of 18.5% versus 0% for single attempts (p=0.005). Difficult cannulation affected 39.8%, with PEP in 19.5% versus 6.5% in easy cases (p=0.043). Balloon dilation was performed in 11.7%, carrying a 50.0% PEP rate versus 6.6% without (p<0.001). Mean 24-hour amylase rose to 269.37 ± 916.20 U/L (PEP: 1 872.58 ± 2 144.47 U/L vs. non-PEP: 57.96 ± 37.12 U/L, p<0.001); lipase to 1 282.89 ± 3 831.04 U/L (PEP: 10 258.08 ± 6 047.55 U/L vs. non-PEP: 99.35 ± 83.20 U/L, p<0.001). ROC AUC for amylase was 0.99 (91.7% sensitivity, 100% specificity) and for lipase 1.00 (100%/98.9%) at >3× ULN (p<0.001).

Conclusion: Post-ERCP pancreatitis is influenced by both patient factors—particularly younger age and female sex—and modifiable procedural variables such as difficult cannulation, balloon dilation, and incomplete stone clearance. Prophylactic measures, notably pancreatic stenting and judicious technique selection, alongside early post-procedure enzyme monitoring, effectively reduce PEP risk.

Keywords: Cholangiopancreatography, ERCP, pancreatic disorders, PEP

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is a widely used therapeutic and diagnostic procedure for managing biliary and pancreatic disorders. However, its associated complications, particularly post-ERCP pancreatitis (PEP), pose significant clinical challenges. PEP is one of the most frequent complications, with incidence rates varying globally, influenced by patient demographics, procedural factors, and operator expertise.[1] Despite advancements in ERCP

techniques and prophylactic measures, PEP remains a critical concern, necessitating robust evaluation and predictive strategies to enhance patient outcomes.[2]

The early prediction of PEP plays a pivotal role in mitigating its severity and guiding timely interventions. Among the various biomarkers studied, serum amylase and lipase levels measured three hours post-procedure have emerged as promising indicators for early diagnosis. Elevated levels of these enzymes are associated with the onset of PEP, yet the exact threshold values and their predictive accuracy continue to be a subject of investigation.[3] Understanding their clinical significance can streamline diagnostic protocols and reduce the delay in initiating appropriate management strategies.[4]

Another emerging area of interest is the neutrophil-lymphocyte ratio (NLR), a simple yet effective inflammatory marker. NLR has been shown to correlate with the severity of systemic inflammation in various medical conditions, including pancreatitis. Its role in predicting the severity of PEP is gaining attention, as it may offer a cost-effective and easily accessible parameter for risk stratification. Investigating the utility of NLR could significantly enhance the ability to identify high-risk patients and optimize resource allocation.[5]

The study of PEP is incomplete without evaluating its complications, which range from mild to life-threatening, including infections, necrosis, and organ failure. Identifying these complications early is essential for reducing morbidity and mortality. Moreover, understanding the associated risk factors, such as patient characteristics, procedural complexity, and comorbid conditions, is crucial for developing preventive strategies. Tailored interventions based on individual risk profiles could play a transformative role in reducing the overall burden of PEP.[6]

The above study aims to address critical gaps in the literature by evaluating the incidence of PEP and investigating its early predictors, including amylase, lipase, and NLR. These insights could help in formulating evidence-based guidelines for clinicians, enabling proactive measures and personalized patient care. By examining the spectrum of complications and associated risk factors, this research seeks to provide a comprehensive understanding of PEP and its management.[7] The findings could contribute to improving procedural safety and patient outcomes, aligning with the broader goal of advancing gastroenterological practices.[8]

Given the significant variability in PEP incidence across different populations and settings, this study also highlights the need for context-specific data. Such data could inform targeted strategies that address regional variations in risk profiles and healthcare resources. The focus on biomarkers and inflammatory indices, combined with a detailed analysis of complications, aims to establish a multifaceted approach to tackling PEP.[9] Ultimately, this research aspires to bridge the gap between theoretical knowledge and clinical application, offering practical solutions to one of the most pressing challenges in ERCP-related care.[10]

MATERIALS AND METHODS

The study was conducted in the Department of Surgery at JN Medical College Hospital (JNMCH), Aligarh Muslim University (AMU), Aligarh, India, over a period of one year. Before beginning the study, ethical clearance was obtained from the Institutional Ethics Committee. 15o participants were selected for the study fulfilling the inclusion and exclusion criteria.

Inclusion Criteria

Patients aged 18 years and above, belonging to both the genders, scheduled to undergo ERCP for various indications, including biliary obstruction, choledocholithiasis, or cholangitis, who were clinically stable and did not have contraindications to undergoing ERCP, willing to provide informed consent.

Exclusion Criteria

Patients with a known history of pancreatitis before undergoing ERCP, those who had severe coexisting comorbidities that contraindicated ERCP (e.g., severe cardiovascular or respiratory diseases), pregnant women, having history of allergy to contrast agents used during the procedure, with ongoing infections or uncontrolled systemic diseases that may interfere with the study outcomes and those refusing to provide consent.

All participants underwent a standard ERCP procedure, which was performed by experienced endoscopists in the hospital's endoscopy suite. Prior to the procedure, patients underwent appropriate preoperative evaluation, including history taking, physical examination, and necessary laboratory investigations. The ERCP procedure was performed using a duodenoscope and other instruments, such as a sphincterotome, guide wire, and balloon catheter. The procedure involved the introduction of a catheter into the duodenum to visualize the biliary and pancreatic ducts and perform interventions such as stone retrieval, stent placement, or sphincterotomy as indicated. Post-procedure, patients were monitored for any signs of pancreatitis, including abdominal pain and elevated pancreatic enzymes (amylase and lipase levels). Blood tests and imaging studies were performed to confirm the diagnosis of post-ERCP pancreatitis.

Post-procedure data were collected, including the occurrence of pancreatitis (based on clinical symptoms and laboratory tests) and any complications associated with the procedure. Follow-up data were obtained on day 3, and patients were monitored for any adverse events. Data were entered into a standardized proforma and analysed

using the SPSS software. A p-value of less than 0.05 was considered statistically significant.

RESULTS

Table 1: Demographic Characteristics (n = 103)

Variable	Category	n (%) / Mean ± SD
Age (years)	Mean ± SD	42.17 ± 13.93
	Range	18–78
	<20	5 (4.9)
	20–30	20 (19.4)
	30–40	33 (32.0)
	40–50	15 (14.6)
	50–60	23 (22.3)
	60–70	6 (5.8)
	>70	1 (1.0)
Sex	Female	74 (71.8)
	Male	29 (28.2)

The study population (n = 103) had a mean age of 42.17 ± 13.93 years, with most patients falling between 30 and 60 years of age, indicating that ERCP was most commonly performed in middle-aged adults. Very young (<20 years) and elderly (>70 years) patients constituted a small proportion of the cohort.

There was a clear female predominance (71.8%), which is consistent with the higher prevalence of biliary disease, particularly choledocholithiasis, among women. Overall, the demographic profile reflects a predominantly middle-aged female population undergoing ERCP in this setting.

Table 2: Indication for ERCP

INDICATION			
		Frequency	**Percent**
Valid	Choledocholithiasis	95	92.2
	Periampullary Carcinoma	8	7.8
	Total	**103**	**100.0**

The overwhelming majority (92.2%) of ERCPs were performed for choledocholithiasis (common bile duct stones), whereas only 7.8% were for periampullary carcinoma. This underscores that stone removal remains the primary therapeutic goal of ERCP in this population. Such a clear predominance helps focus preventive strategies—like stent placement or pharmacologic prophylaxis—on stone-related interventions rather than malignancy management.

Table 3: Procedure-Related Factors (n = 103)

Variable	Category	n (%)
Guidewire use	Yes	103 (100)
Cannulation attempts	Single	38 (36.9)
	Multiple	65 (63.1)
Difficult cannulation	No	62 (60.2)
	Yes	41 (39.8)
Sphincterotomy	No	22 (21.4)
	Yes	81 (78.6)
Balloon dilatation	No	91 (88.3)
	Yes	12 (11.7)

All patients underwent guidewire-assisted cannulation, reflecting standardized procedural practice. Multiple cannulation attempts were required in nearly two-thirds of cases (63.1%), and difficult cannulation was encountered in 39.8% of patients, indicating a substantial procedural complexity. Sphincterotomy was performed in the majority of cases (78.6%), consistent with the high prevalence of stone-related pathology. Balloon dilatation was used in a smaller proportion of patients (11.7%), suggesting selective application in cases requiring additional ductal access or stone extraction. Overall, these findings indicate that most procedures involved advanced endoscopic interventions, with a significant proportion experiencing technical difficulty.

Table 4: Papilla Morphology by Pancreatitis Status

Papilla Morphology	Pancreatitis: No	Pancreatitis: Yes	Total	P value
Bulging	14	3	17	0.003
Flat	3	3	6	
Normal	69	4	73	

Stenosed	5	2	7	
Total	**91**	**12**	**103**	

Of 103 patients, bulging papillae carried the highest PEP rate: 3/17 (17.6%) versus 14/17 without PEP (82.4%), p=0.003. Flat papillae had equal PEP and non-PEP counts (3/6 each), while normal papillae saw 4/73 (5.5%) PEP, and stenosed papillae 2/7 (28.6%) PEP. Bulging and stenosed morphologies appear particularly prone to pancreatitis, likely due to altered papillary anatomy and increased manipulation. Recognizing these morphologic risk factors can guide intensified prophylaxis (e.g., NSAIDs, stenting) when encountering non-normal papillae.

Table 5: Stone Clearance by Pancreatitis Status

Stone Clearance	Pancreatitis: No	Pancreatitis: Yes	Total	P value
No	9	5	14	0.003
Yes	82	7	89	
Total	**91**	**12**	**103**	

Incomplete clearance correlated with higher PEP: 5/14 (35.7%) versus 7/89 (7.9%) when stones were fully removed (p=0.003). Residual stones likely reflect more difficult procedures with prolonged manipulation. Achieving complete clearance on first attempt may reduce PEP risk and need for repeat interventions.

Table 6: Stent Placement by Pancreatitis Status

Stent	Pancreatitis: No	Pancreatitis: Yes	Total	P value
No	26	7	33	0.038
Yes	65	5	70	
Total	**91**	**12**	**103**	

Patients without prophylactic stent had higher PEP: 7/33 (21.2%) versus 5/70 (7.1%) with stent (p=0.038). Stenting likely mitigates ductal hypertension and pancreatic juice stasis. This significant reduction supports routine stent use in high-risk cases to prevent PEP.

Table 7: Serum Enzyme Levels by Pancreatitis Status

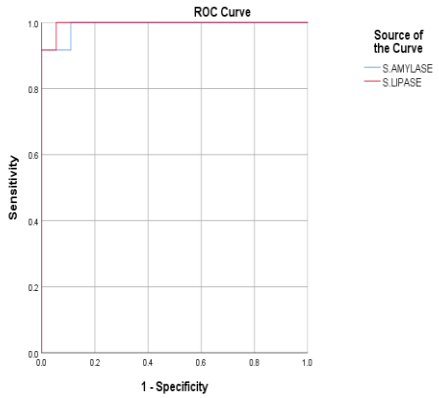
T test Group statistics						
Pancreatitis_Cat		**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**	**P value**
S.AMYLASE	**NO**	91	57.96	37.122	3.891	<0.001
	YES	12	1872.58	2144.472	619.056	
S.LIPASE	**NO**	91	99.35	83.203	8.722	<0.001
	YES	12	10258.08	6047.550	1745.777	

Mean amylase was 1872.6 ± 2 144.5 U/L in PEP versus 58.0 ± 37.1 U/L without (p<0.001). Mean lipase was 10 258.1 ± 6 047.6 U/L in PEP versus 99.4 ± 83.2 U/L without (p<0.001). These dramatic enzyme elevations distinguish PEP from benign post-procedure rises, supporting their use as sensitive and specific early biomarkers.

Table 8: ROC Analysis for Post-ERCP Pancreatitis

Test Result Variable	Area Under Curve (AUC)	Std. Error	P value	Lower Bound (95% CI)	Upper Bound (95% CI)	Sensitivity	Specificity
S. Amylase	0.99	0.010	<0.001	0.972	1.000	91.7%	100%
S. Lipase	1.00	0.005	<0.001	0.985	1.000	100%	98.9%

ROC curves showed amylase AUC 0.99 (95% CI 0.97–1.00; p < 0.001) and lipase AUC 1.00 (95% CI 0.99–1.00; p < 0.001). Amylase sensitivity/specificity were 91.7%/100%, and lipase 100%/98.9%. These metrics demonstrate excellent diagnostic performance of both enzymes, with lipase marginally superior. Employing enzyme thresholds (>3× ULN) yields highly reliable early PEP detection.



DISCUSSION

The primary aim of the study was to delineate the constellation of patient-related and procedural factors that predispose to post-ERCP pancreatitis (PEP) and to evaluate how systematic risk mitigation and post-procedure monitoring can improve patient outcomes. By retrospectively analyzing 103 consecutive ERCP cases—capturing demographics, clinical presentations, detailed procedural metrics (including cannulation attempts, papillary morphology, sphincterotomy technique, balloon dilation, and stent placement), and biochemical and symptomatic data at fixed post-ERCP time points— this research sought to quantify the individual and combined impact of each variable on PEP incidence. By identifying modifiable risk factors—such as limiting cannulation attempts, reserving balloon dilation for strictly defined cases, prioritizing complete stone clearance, and ensuring prophylactic pancreatic stent placement—the study offers actionable insights that can be directly translated into quality improvement initiatives.

In cohort of 103 ERCP patients (mean age 42.17 ± 13.93 years), the predominance of younger adults (71% <50 years) and females (71.8%) aligns with prior studies identifying younger age and female sex—especially young women—as key risk factors for post-ERCP pancreatitis (PEP). Rustagi and Jamidar,[11] and Fujita et al,[12] demonstrated significantly higher PEP rates in younger and female patients, particularly in high-risk groups, while Lee and Park,[13] reported increased sensitivity to procedural trauma in younger individuals. In contrast, transplant-based studies reported higher pancreatitis rates driven by anatomical and procedural complexity rather than age or sex.[14,15] These findings support incorporating age and sex into ERCP risk stratification and underscore the need for aggressive prophylaxis, such as rectal NSAIDs and selective pancreatic stenting, particularly in young female patients.

Choledocholithiasis accounted for the overwhelming majority of ERCP indications (92.2%) in above study, with only 7.8% performed for periampullary carcinoma. Rustagi and Jamidar,[11] emphasized that choledocholithiasis remains the leading ERCP indication globally, with stone-related ERCPs inherently posing significant pancreatitis risks due to prolonged papillary manipulation and ductal pressure increases; PEP rates in stone-related ERCP without prophylaxis reached approximately 15%, notably decreasing with prophylactic stents or NSAIDs. Above results closely mirrored Fujita et al,[12] who analyzed a cohort predominantly undergoing ERCP for biliary stones and found procedural complexity linked to stone extraction significantly predicted higher PEP rates (12.3% overall; 27% in high-risk groups). Lee and Park,[13] further highlighted stone extraction as a dominant ERCP indication associated with significant pancreatitis risk, recommending pancreatic stenting as highly effective in reducing severe PEP (<1%) despite potential complications (5%-10%).

In above study, multiple cannulation attempts, difficult cannulation, and balloon papillary dilatation were strongly associated with significantly higher post-ERCP pancreatitis (PEP) rates, whereas sphincterotomy alone did not independently increase risk. These findings align closely with Rustagi and Jamidar,[11] who demonstrated that repeated cannulation, traumatic papillary manipulation, and ductal hypertension—particularly in the absence of prophylaxis—markedly elevate PEP risk. Fujita et al,[12] incorporated difficult cannulation and procedural complexity into a validated risk-scoring system, showing substantially higher pancreatitis rates in high-risk groups. Lee and Park,[13] further emphasized limiting cannulation attempts, early transition to advanced techniques, and selective use of balloon dilation, with prophylactic pancreatic stenting and NSAIDs significantly reducing severe PEP. Similarly, Shehta et al,[15] reported markedly increased pancreatitis rates in complex anatomical settings, especially when difficult cannulation and advanced interventions were required. Collectively, these data reinforce the importance of procedural discipline, early escalation strategies, and aggressive prophylaxis in high-risk ERCP cases to minimize pancreatitis and improve patient outcomes.

Complete ductal stone clearance was achieved in 86.4% (89/103) of our patients, leaving 13.6% (14/103) with residual stones. The PEP rate was

35.7% (5/14) in those with incomplete clearance versus 7.9% (7/89) when stones were fully removed (p = 0.003). This substantial disparity highlights that difficult or incomplete extraction—often requiring extended manipulation, repeated balloon sweeps, or adjunctive lithotripsy—dramatically increases papillary trauma and intraductal pressure. Rustagi and Jamidar,[11] identified prolonged stone extraction and repeated ductal instrumentation as core procedural risk factors, noting that prophylactic measures reduced PEP from approximately 15% in these high-risk scenarios to single digits when appropriately implemented. Fujita et al,[12] also included incomplete clearance within their high-risk procedural variables, observing a 27% PEP rate in patients scoring ≥4 versus 5% in low-risk groups (AUC = 0.85). Cengiz et al,[14] did not specifically analyze clearance but reported that persistent ductal obstruction post-PEP contributed to subsequent nonalcoholic fatty pancreas disease in 21.9% of patients, linking residual stones to longer-term parenchymal changes. Collectively, these studies affirm that achieving complete stone clearance on the first ERCP session is pivotal: it reduces PEP risk, decreases need for repeat procedures, and may prevent chronic pancreatic sequelae.

Prophylactic pancreatic stents were placed in 68.0% (70/103) of our patients, leaving 32.0% without stenting. PEP occurred in 7.1% (5/70) of stented patients compared to 21.2% (7/33) in the non-stented group (p = 0.038). This significant reduction underscores stent efficacy in maintaining ductal drainage and preventing enzymatic stasis. Rustagi and Jamidar,[11] demonstrated that stenting, especially when combined with rectal indomethacin, reduced PEP rates from 15% in high-risk patients to under 10%, with single-digit incidences in those receiving both interventions. Lee and Park,[13] elevated stenting as the most potent prophylactic measure, achieving severe PEP rates below 1%, albeit acknowledging a 5–10% complication rate from stent migration or ductal injury. In contrast, Shehta et al.'s,[15] liver transplant cohort, which placed stents less frequently due to anatomical complexities, suffered a 38.8% PEP rate, highlighting the protective benefit of stenting even in challenging cases. Overall, the data reinforce prophylactic stent placement as a cornerstone of PEP prevention, particularly in high-risk settings (difficult cannulation, balloon dilation, prior pancreatitis).

At 24 hours post-ERCP, mean serum amylase in our cohort rose to 269.37 ± 916.20 U/L (range 22–7 345) and lipase to 1282.89 ± 3831.04 U/L (range 26–17 843). Among the 12 PEP patients, mean amylase was 1872.58 ± 2144.47 U/L versus 57.96 ± 37.12 U/L in non-PEP (p < 0.001); mean lipase was 10258.08 ± 6047.55 U/L versus 99.35 ± 83.20 U/L (p < 0.001). These stark contrasts underscore dramatic enzyme surges in PEP cases. Uchino et al,[16] similarly found that CT-confirmed PEP patients exhibited mean amylase of 1306 ± 833 IU/L compared to 786 ± 315 IU/L in those without CT findings (p = 0.0012), proposing an amylase cutoff of 795 IU/L for imaging referral. Our data not only support their threshold but extend it by demonstrating even higher mean levels in clinically overt PEP. Rustagi and Jamidar,[11] reviewed enzymatic predictors, noting that elevations ≥3× ULN correlate with PEP risk, yet emphasized the need for combined prophylaxis to blunt these rises. Fujita et al.'s,[12] risk score focused on procedural variables but acknowledged that enzyme kinetics provide critical adjunctive information, even if not formally included in their model (AUC = 0.85). Lee and Park,[13] highlighted that while lipase offers greater specificity than amylase, both remain indispensable for early detection, recommending routine 24-hour measurement to capture delayed onset cases and guide timely management. Above study findings affirm that 24-hour enzyme assays are essential: amylase and lipase elevations not only confirm PEP diagnosis but, when extreme, correlate with severity. Standardizing enzyme measurement at 24 hours post-ERCP—and integrating these values with clinical and inflammatory markers—will enable rapid PEP identification and appropriate escalation of care.

In the above study, ROC analysis demonstrated excellent early diagnostic performance for post-ERCP pancreatitis (PEP), with amylase achieving an AUC of 0.99 (95% CI 0.97–1.00; p < 0.001) and lipase reaching 1.00 (95% CI 0.99–1.00; p < 0.001). At a cutoff of >3× ULN, amylase showed 91.7% sensitivity and 100% specificity, while lipase achieved 100% sensitivity and 98.9% specificity, highlighting their near-perfect ability to detect clinically significant PEP. Uchino et al,[16] proposed an amylase cutoff of 795 IU/L, but without reporting AUC, and their sensitivity and specificity were lower due to inclusion of asymptomatic hyperamylasemia cases. Rustagi and Jamidar,[11] emphasized the importance of enzyme elevations and prophylaxis in modulating PEP incidence but did not provide ROC-based analyses. Fujita et al,[12] reported an AUC of 0.85 for a combined procedural risk score including age, difficult cannulation, and duct injections, demonstrating good predictive value, yet still inferior to direct enzymatic assessment. Lee and Park,[13] recommended integrating enzyme thresholds with clinical risk stratification, noting prior meta-analyses reporting enzyme AUCs around 0.9 to optimize early PEP detection while reducing unnecessary imaging. In high-risk groups such as liver transplant recipients, Shehta et al,[15] observed that amylase elevations >3× ULN correlated with prolonged hospital stays and increased complications, though ROC analyses were not performed. Collectively, these findings reinforce the superior diagnostic accuracy of 24-hour amylase and lipase measurements, supporting their routine use as front-line tools in post-ERCP monitoring and early PEP detection.

The study's strengths include its real-world evaluation of 103 consecutive ERCPs, capturing diverse patient demographics, comorbidities, procedural details, and standardized clinical and biochemical markers, enabling robust ROC analysis for early PEP detection. Detailed documentation of cannulation, sphincterotomy, balloon dilation, and stent use allowed correlation of procedural factors with PEP risk, while outcome metrics such as technical success and hospital stay enhance clinical relevance. Consistent use of wire-guided cannulation and selective prophylaxis supports external validity and practical applicability. Limitations include its retrospective, single-center design, incomplete data for some markers, lack of standardized prophylaxis, small subgroup sizes, and absence of long-term follow-up or patient-reported outcomes. Future studies should employ prospective, multicenter designs with standardized data collection, emerging biomarkers, predictive analytics, and interventional trials to optimize PEP prevention and personalized ERCP care.

CONCLUSION

In conclusion, the study highlights that post-ERCP pancreatitis is influenced by both patient factors—particularly younger age and female sex—and modifiable procedural variables such as difficult cannulation, balloon dilation, and incomplete stone clearance. Prophylactic measures, notably pancreatic stenting and judicious technique selection, alongside early post-procedure enzyme monitoring, effectively reduce PEP risk. Integrating demographic, procedural, and biochemical indicators into standardized ERCP protocols can optimize patient safety and outcomes. Future prospective, multicenter studies incorporating biomarkers, risk scoring, and predictive models will further refine personalized PEP prevention strategies, ensuring ERCP remains both effective and safe.

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