

Rectal Indomethacin plus Lactated Ringer's for Prophylaxis of Post-ERCP Pancreatitis in Children

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Abstract

Background and study aims: Pediatric data on post-endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis (PEP) prophylaxis remains limited. This study evaluated the effectiveness and safety of combined rectal indomethacin and lactated Ringer's (LR) as prophylaxis for PEP in children undergoing ERCP.

Patients and methods: We retrospectively reviewed all pediatric ERCPs performed at a single tertiary center (2012–2025). The study group consisted of procedures performed after 2021, when a standardized prophylaxis protocol (100 mg rectal indomethacin before ERCP plus LR at 2.5 L·m⁻², started 2 hours before and continued 6 hours after) was implemented. Procedures performed before 2021 served as the control group. Primary and secondary endpoints were the development of PEP and cholangitis, respectively. Analyses considered American Society for Gastrointestinal Endoscopy (ASGE) procedural complexity, stent placement/type, and naive papilla status.

Results: Seventy-five children underwent 95 ERCPs (prophylaxis group: 23 patients/38 procedures; control group: 55 patients/65 procedures). Baseline demographic and procedural characteristics were similar between the prophylaxis and control groups. Post-ERCP pancreatitis developed in 13.2% of procedures in the prophylaxis group and 13.8% in the control group (RD -0.7%; 95% CI -18.5 to 19.9; *p* = 1.000). Cholangitis developed in 5.3% of procedures in the prophylaxis group and 7.7% in the control group (RD -2.4%; 95% CI -15.3 to 14.0; *p* = 1.000). Adjustment for stent type did not meaningfully alter the associations between prophylaxis and outcomes. All PEP cases were mild to moderate. No treatment-related adverse events—including indomethacin-associated gastrointestinal or renal complications, or fluid-overload events—were observed in either group.

Conclusions: Combined rectal indomethacin plus LR was feasible and well tolerated in pediatric ERCP but did not significantly reduce PEP or cholangitis. These findings highlight the need for larger, multicenter pediatric trials to define optimal prophylaxis. (*Acta gastroenterol belg.*, 2026, 89, 25-31).

Keywords: Preventive therapy, hydration protocol, nonsteroidal anti-inflammatory drug.

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) remains a cornerstone endoscopic modality for the diagnosis and, increasingly, the treatment of pancreatobiliary disease. With the widespread use of magnetic resonance cholangiopancreatography and endoscopic ultrasonography, contemporary ERCP is now performed primarily for therapeutic purposes (1). Although experienced endoscopists achieve high technical success rates with an acceptable safety profile, adverse events—including post-ERCP pancreatitis (PEP), hemorrhage, cholangitis, cholecystitis, and perforation—occur in up to 10% of adult cases in some series (2). The reported incidence of PEP in adults is 3.5–10.2% (3). In

children, the rates are more variable, ranging from 3–16% (4). Early meta-analytic studies report an overall PEP incidence of about 10% and a mortality of around 0.7% (5), although these numbers can differ by age, indication, and procedure complexity. The clinical and economic burden of PEP has placed prophylaxis at the forefront of peri-procedural management. The adult evidence base supports a coordinated approach incorporating single-dose rectal nonsteroidal anti-inflammatory drugs (NSAIDs), placement of a prophylactic pancreatic duct stent (PPS) in high-risk scenarios, and aggressive lactated Ringer's (LR) hydration in selected contexts (6,7). Within this framework, rectal NSAIDs carry a strong recommendation and constitute the backbone of standard care; however, the incremental benefit of LR beyond NSAIDs has not been consistently demonstrated in randomized data when NSAIDs are already used (8). In pediatrics, however, the evidence remains limited and largely retrospective. The European Society of Gastrointestinal Endoscopy (ESGE) and the European Society of Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) jointly endorse the use of rectal NSAIDs in adolescents, while emphasizing the need for adequately powered randomized trials. Pediatric data are particularly scarce regarding optimal dosing, timing, and combination strategies, such as NSAIDs with LR, with or without PPS (9).

This knowledge gap justifies systematic reporting of institutional experience in pediatric PEP prophylaxis. We therefore evaluated the effect of introducing a combined prophylactic regimen of rectal indomethacin and peri-procedural hydration with LR on the incidence of PEP and cholangitis in children at our center.

Methods

Ethics Statement

Ethical approval for this study was obtained from the Ethics Committee of Çukurova University School

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Study Design and Population

We conducted a retrospective, single-center cohort study of children ERCP at the Department of Pediatric Gastroenterology, Cukurova University Faculty of Medicine, from 2012 through 2025. Eligible participants were <18 years of age at the time of ERCP. We excluded patients with active pancreatitis or cancer/tumor metastasis, as well as cases with insufficient documentation or missing primary/secondary outcome assessments.

Procedural Details

All ERCPs were performed under general anesthesia using various combinations of propofol, fentanyl, ketamine, and midazolam, with standard intraoperative monitoring by an anesthesia team. Drug dosing reflected routine clinical practice and was therefore not itemized.

Beginning in 2021, our center instituted routine prophylaxis consisting of rectal indomethacin plus LR. Accordingly, procedures performed from 2021 onward constituted the prophylaxis arm (combined prophylaxis administered), whereas those performed before 2021 comprised the control arm (no prophylaxis). For analytic purposes, the study period was divided into three eras: 2012–2016, 2017–2020, and 2021–2025. The 2021–2025 era corresponded to the prophylaxis period, during which all patients routinely received rectal indomethacin plus LR hydration. The two earlier eras (2012–2016 and 2017–2020) constituted the control period, and were analyzed separately to assess secular trends over time. The prophylaxis regimen entailed initiating Lactated Ringer's solution at 2.5 L·m⁻² two hours before ERCP. A 100-mg dose of rectal indomethacin was administered immediately prior to cannulation. Hydration with LR was then continued at the same rate for six hours after the procedure. Following this period, 0.9% normal saline was infused for at least 24 hours at an equivalent volume. Contraindications and protocol deviations were documented in the clinical record and abstracted for analysis. Two adult gastroenterologists (O.U. and U.K.) performed ERCP procedures during 2021–2025, whereas a single operator (O.U.) conducted all procedures in the earlier period. To minimize year–operator collinearity, operator identity was modeled as a period-specific covariate restricted to the post-2021 period.

Outcomes

The primary outcome was PEP adjudicated at 24 hours, defined by the presence of ≥ 2 of the following:

(i) characteristic abdominal pain, (ii) serum amylase and/or lipase $\geq 3\times$ the upper limit of normal, and (iii) radiologic evidence of pancreatitis. The severity of PEP was graded as mild, moderate, or severe according to the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) criteria (mild: no organ failure and no local or systemic complications; moderate: transient organ dysfunction <48 h or local/systemic complications; severe: persistent organ failure >48 h) and patients who developed PEP were managed in accordance with NASPGHAN recommendations (10). Secondary outcomes included post-ERCP cholangitis, procedure-related bleeding/perforation, and any emergency revisits/hospitalizations within 7 and 30 days. Cholangitis was defined according to the Tokyo Guidelines 2018, integrating clinical features (fever or right upper quadrant pain), laboratory abnormalities (leukocytosis, elevated C-reactive protein, and cholestatic markers), and imaging evidence of biliary obstruction or dilatation (11). In all patients, amylase, lipase, and hematocrit were reassessed at 4 and 24 hours after ERCP. Abdominal ultrasonography, computed tomography, and magnetic resonance imaging was performed as clinically indicated.

Statistical Analysis

Descriptive statistics are presented as mean \pm standard deviation (SD) or median (range/interquartile range, as appropriate) for continuous variables, and as n (%) for categorical variables. Primary, procedure-level comparisons report risk differences with Newcombe 95% confidence intervals (CI) and two-sided Fisher's exact p-values; the number needed to treat is provided where informative. For stratified analyses by stent type, common odds ratios and corresponding p-values were estimated using the Cochran–Mantel–Haenszel (CMH) method. A patient-level sensitivity analysis was performed by restricting the dataset to the first ERCP (naive papilla). To account for within-patient correlation due to repeated procedures and potential secular learning effects, calendar year and (post-2021 only) operator identity were included as covariates. A two-sided $\alpha = 0.05$ was considered statistically significant.

Bias and Limitations

The before–after design is inherently vulnerable to secular trends and confounding by indication; inclusion of calendar year and operator mitigates but does not eliminate these sources of bias. Furthermore, technical difficulty metrics (e.g., difficult cannulation, number of attempts, procedure duration) were not systematically recorded, limiting comprehensive adjustment for procedural complexity beyond American Society for Gastrointestinal Endoscopy (ASGE) level (1,6) and stent variables.

Results

A total of five cases were excluded according to prespecified criteria. After 2021 (prophylaxis period), three patients were excluded: one with malignant-mass-related bile duct obstruction and two with choledocholithiasis and acute pancreatitis. Before 2021 (control period), two patients were excluded due to missing laboratory data. Following these exclusions, 75 children underwent 95 ERCP procedures: 38 in the prophylaxis arm (23 patients) and 65 in the control arm (55 patients). Baseline characteristics were broadly comparable with respect to age, sex, indication spectrum, ASGE procedural risk level, pancreatic duct cannulation, and stent placement (pancreatic or biliary),

with no clinically relevant differences (Table 1).

At the procedure level, primary outcomes did not differ significantly between groups. PEP developed in 13.2% of procedures in the indomethacin plus LR group and 13.8% in controls ($p = 1.00$). Cholangitis rates were likewise similar (5.3% vs 7.7%; $p = 1.00$) (Table 2). In the sensitivity analysis restricted to the first ERCP per patient, the comparison yielded no meaningful differences. PEP developed in 17.4% vs 9.1% ($p = 0.437$), and cholangitis in 4.3% vs 5.5% ($p = 1.00$) (Table 2).

Calendar-period stratification (2012–2016, 2017–2021, and 2021–2025-prophylaxis period) did not reveal temporal effects for either outcome (PEP: $p = 0.765$; cholangitis: $p = 0.411$ by 3×2 Fisher–Freeman–

Table 1. — Characteristics of patients.

Variable	Indomethacin + LR (N=23; procedures=38)	Control (N=55; procedures=65)	P
Age (years), mean ± SD	13.10 ± 3.12	12.75 ± 3.65	0.68
Sex (M/F)	8 / 15	23 / 32	0.74
Indications (overall)			0.57
Choledocholithiasis	18	31	
Sclerosing cholangitis	1	2	
Biliary dilatation	4	2	
Choledochal cyst	1	6	
Recurrent or chronic pancreatitis	10	16	
Stent removal/revision	5	8	
ASGE procedural risk level (overall)			0.78
Level I	14	23	
Level II	10	14	
Level III	14	28	
Level IV	0	0	
Pancreatic duct cannulation	6	9	0.78
Biliary stent placement	8	15	0.99
Pancreatic duct stent placement	5	4	0.28

ERCP, endoscopic retrograde cholangiopancreatography; LR, lactated Ringer’s; ASGE, American Society for Gastrointestinal Endoscopy; SD, standard deviation.

Table 2. — PEP and cholangitis in all procedures and first ERCP .

Outcome	Subgroup	Indomethacin + LR	Control	RD (%)	95% CI	p
PEP	All procedures	5/38 (13.2%)	9/65 (13.8%)	-0.7	-18.5 to 19.9	1.000
PEP	First ERCP (Naive papilla)	4/23 (17.4%)	5/55 (9.1%)	+8.3	-12.6 to 33.2	0.437
Cholangitis	All procedures	2/38 (5.3%)	5/65 (7.7%)	-2.4	-15.3 to 14.0	1.000
Cholangitis	First ERCP (Naive papilla)	1/23 (4.3%)	3/55 (5.5%)	-1.1	-14.1 to 19.1	1.000

PEP, post-ERCP pancreatitis; LR, rectal indomethacin plus lactated Ringer’s; RD, risk difference; CI, confidence interval.

Halton exact test), suggesting broadly stable rates across epochs (Table 3).

After stratification by stent status/type (pancreatic, biliary, or none), rectal indomethacin plus LR did not significantly affect the incidence of PEP or cholangitis. In our cohort, biliary stents were placed in 8/38 procedures in the prophylaxis arm and 15/65 procedures in controls, while pancreatic duct stents were used in 5/38 and 4/65 procedures, respectively (Table 1). The CMH common odds ratio was 0.97 for PEP (p = 0.95) and 0.68 for cholangitis (p = 1.00), indicating no significant preventive benefit across stent strata (Table 4).

Analyses by ASGE procedural risk level were limited by small subgroup sizes, and no consistent or statistically robust separation between arms was observed across Levels I–III (no Level IV procedures) (Table 5).

No treatment-related adverse events—including indomethacin-associated gastrointestinal or renal complications, or fluid-overload events—were observed in either group.

Discussion

Post-endoscopic retrograde cholangiopancreatography pancreatitis continues to impose a clinically

and economically meaningful burden even in high-volume, expert centers. Contemporary prevention follows a multilayered approach. Rectal nonsteroidal anti-inflammatory drugs (mainly indomethacin or diclofenac) form the universal foundation when not contraindicated. Pancreatic duct stenting is added for high-risk patients, and periprocedural LR hydration is tailored to the clinical and procedural context (6,12–14). In unselected adults, guidelines strongly endorse rectal NSAIDs, recommend PPS for high-risk cases, and provide conditional support for aggressive hydration in specific settings (6).

Accumulating evidence, including several meta-analyses, indicates that a single 100-mg rectal dose of indomethacin confers a significant reduction in PEP risk (14-16). By contrast, randomized controlled trials have not demonstrated a consistent incremental benefit from adjunctive LR hydration when added to NSAID prophylaxis (6). In high-risk cohorts, however, the combination of an NSAID with prophylactic pancreatic stenting has shown superior protective efficacy relative to NSAID monotherapy (13). Adult systematic reviews place overall PEP incidence around 3.5–10.2% with low but non-negligible severe events (3). Pediatric evidence remains comparatively limited. In a Mayo Clinic cohort of 224 children (343 ERCPs), PEP prevalence was 2.5%

Table 3. — PEP and cholangitis across study periods .

Period	Procedures (n)	PEP (n, %)	Cholangitis (n, %)	p
2012–2016	28	2 (7.1%)	4 (14.3%)	PEP, 0.765
2017–2020	37	3 (8.1%)	5 (13.5%)	
2021–2025 (Prophylaxis)	38	5 (13.2%)	2 (5.3%)	Cholangitis, 0.411

PEP, post-ERCP pancreatitis; ASGE, American Society for Gastrointestinal Endoscopy.

Table 4. — PEP and cholangitis stratified by stent type.

Outcome	Indomethacin + LR	Control	RD (%)	95% CI	p	CMH OR	CMH p
PEP	5/38 (13.2%)	9/65 (13.8%)	−0.7	−18.5 to 19.9	1.00	0.97	0.94
Cholangitis	2/38 (5.3%)	5/65 (7.7%)	−2.4	−15.3 to 14.0	1.00	0.68	1.00

PEP, post-ERCP pancreatitis; LR, lactated Ringer’s; RD, risk difference; CI, confidence interval; CMH, Cochran–Mantel–Haenszel. Procedure-level data were analyzed. Risk differences are presented as percentage points with Newcombe 95% confidence intervals. Two-sided Fisher’s exact tests were used to derive p-values. Cochran–Mantel–Haenszel (CMH) common odds ratios and corresponding p-values were calculated after stratification by stent status/type (pancreatic, biliary, or none). Stent distribution by group is provided in Table 1 (biliary stents: 8/38 vs 15/65; pancreatic stents: 5/38 vs 4/65). CMH odds ratios reflect stratification by these stent categories.

Table 5. — PEP and cholangitis by ASGE Risk Level.

ASGE Risk Level	Indomethacin + LR		Control		PEP		Cholangitis	
	PEP	Cholangitis	PEP	Cholangitis	OR (95% CI)	p	OR (95% CI)	p
Level 1	0	0	0	2	1.39 (0.38-5.07)	0.53	0.58 (0.10-3.28)	0.61
Level 2	1	2	2	2				
Level 3	4	0	5	1				
Level 4	0	0	0	0				

PEP, post-ERCP pancreatitis; ASGE, American Society for Gastrointestinal Endoscopy; OR, odds ratio; CI, confidence interval.

in those without chronic pancreatitis and 4.96% overall, with higher rates observed in chronic pancreatitis and therapeutic interventions. Broader pediatric summaries cite rates of ~2–7% in general populations and higher in high-risk subsets, which contextualize the magnitude of any prophylactic effect observed in our population (17). The ESGE/ESPGHAN joint guideline supports rectal NSAIDs in children aged ≥ 14 years while underscoring the need for large pediatric randomized trials to define LR dosing/timing and clarify the net benefit of PPS (9). Against this background, we implemented at our center a standardized regimen—single-dose rectal indomethacin plus periprocedural LR—and evaluated its association with pediatric PEP and cholangitis after ERCP. In a before–after design, the proportion of PEP events during the prophylaxis period remained essentially comparable with the pre-implementation era, whereas cholangitis showed a downward trend without statistical certainty. A patient-level sensitivity analysis restricted to the first ERCP (naive papilla) yielded a consistent direction of effect. No treatment-related adverse events—including indomethacin-associated gastrointestinal or renal complications or fluid-overload events—were observed, indicating a favorable tolerability profile for the rectal indomethacin plus LR regimen in children.

To date, neither the combination of rectal NSAID prophylaxis with periprocedural LR hydration nor the individual components have been evaluated for PEP prevention in children. Pediatric data relevant to LR are entirely indirect, as existing studies pertain to general acute pancreatitis rather than procedure-related pancreatitis. The largest such study, using the Pediatric Health Information System (PHIS, a U.S. multicenter administrative database; $n = 1,581$), exclusive use of LR during the first 48 hours was associated with a shorter length of stay and lower hospitalization costs compared with normal saline. Multivariable analysis confirmed that normal saline use was associated with more than a threefold increased risk of prolonged hospitalization (18). Although this study did not specifically address PEP, it strengthens the rationale for choosing LR in pediatric prophylaxis protocols. Similarly, evidence for NSAIDs in children, while sparse, is encouraging. In the only prospective randomized pediatric trial, intravenous ibuprofen showed a nonsignificant reduction in PEP incidence (7% vs 17%) and significantly lower post-procedural pain scores without increased adverse events, supporting both feasibility and safety but emphasizing the urgent need for adequately powered trials (19).

Our stent-related findings merit nuanced interpretation through the lens of confounding by indication. All children who received PPS carried a diagnosis of chronic pancreatitis, and prophylactic stenting was selected despite the absence of a tight stricture on imaging—an enrichment for an intrinsically high-risk phenotype. Chronic pancreatitis is associated with altered ductal architecture, papillary irritability, and repeated manipulation, all of which plausibly increase

susceptibility to PEP. Decisions to place a PPS are likewise often driven by difficult cannulation, unintended pancreatic duct access, or challenging papillary anatomy, each independently contributing to elevated PEP risk. Consequently, the higher observed PEP proportion among stented cases likely reflects risk clustering and selection bias rather than a direct effect of stenting itself. Adult randomized data further indicate that, when technically feasible and appropriately indicated, NSAID + PPS remains preferable to NSAID alone in high-risk settings (13).

The hydration protocol used in this study—a continuous-rate LR infusion initiated two hours before ERCP and continued for six hours afterward—differs in both timing and duration from several adult regimens that combine an initial bolus with prolonged infusion (8). Such differences may modulate effect size; moreover, pediatric hemodynamics may favor the tolerability of steady-rate regimens. Importantly, in our series the combination regimen did not shift the severity spectrum toward worse outcomes and was not associated with major complications, reinforcing a reassuring safety profile. Observational pediatric data in acute pancreatitis—outside the ERCP setting—also suggest associations between early LR use and shorter length of stay, lending indirect support to LR selection in pediatric protocols (18).

Analytically, we incorporated calendar year and operator as covariates to mitigate secular trends and learning/operator effects, and modeled clustering from repeated procedures using generalized estimating equations and mixed-effects approaches. Even so, comprehensive adjustment for residual confounding is limited by the lack of systematically recorded technical-difficulty metrics that strongly influence PEP risk—difficult cannulation, number of attempts, procedure duration, and unintended pancreatic duct access. This constraint is particularly germane to interpreting the stent–PEP relationship, as the same technical factors can drive both PPS decisions and PEP risk. Prospective, standardized capture of these metrics will strengthen the accuracy and generalizability of future estimates.

Taken together, our findings support a pediatric prophylaxis framework that aligns with the adult-derived paradigm. Rectal NSAIDs serve as the foundational measure when not contraindicated. Placement of a PPS functions as a selective adjunct in the presence of high-risk features and when technically feasible. Hydration with LR represents a targeted, closely monitored option for hemodynamically and clinically appropriate candidates. Full pediatric translation will require adequately powered, multicenter prospective studies incorporating age/weight-informed dosing and timing, prespecified high-risk phenotypes (e.g., naive papilla, chronic pancreatitis), and explicit accounting for repeated procedures.

This study has several limitations. First, its before–after design is inherently prone to confounding by

indication and secular trends, which cannot be fully eliminated despite inclusion of calendar year and operator covariates. Second, technical difficulty metrics—such as cannulation attempts, procedure duration, and inadvertent pancreatic duct access—were not systematically documented, limiting adjustment for procedural complexity. Third, the relatively small sample size and low event rates restrict statistical power to detect modest differences between arms. Fourth, this was a single-center, retrospective analysis, which may limit generalizability beyond comparable institutional contexts. Finally, confounding by indication remains possible, particularly within the PPS subgroup, as stenting was primarily undertaken in children with chronic pancreatitis, who intrinsically represent a higher-risk phenotype for post-ERCP pancreatitis.

In conclusion, this single-center experience demonstrates the feasibility and safety of a standardized rectal indomethacin plus LR protocol in pediatric ERCP. Although we did not observe a material reduction in event rates, confinement of PEP to mild–moderate severity and the absence of severe PEP are clinically reassuring. Future multicenter pediatric studies that integrate phenotype-based stratification, operator/technical metrics, and age/weight-sensitive dosing and hydration schemas—and are powered to exclude small-to-moderate absolute risk differences—are warranted to provide definitive answers.

Declarations

Conflicts of Interest and Source of Funding: The authors declare no conflicts of interest. This study received no external funding from any public, commercial, or not-for-profit sectors.

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