IJNMI

Research Article

Efficacy, Safety, and Tolerability of a Fixed-Dose Combination of Camylofin and Diclofenac in the Management of Moderate-to-Severe Colic: A Phase IV Clinical Study

Devesh Kumar[1], Archna Khurana[2]

[1]IR Innovate Research Private Limited, Noida, Uttar Pradesh, India, [2]Department of Clinical Research, Texila American University, Coimbatore, Tamil Nadu, India

Abstract

Background: Colic is a common cause of severe abdominal pain, often requiring pharmacological intervention for symptom relief. Traditional treatment approaches include non-steroidal anti-inflammatory drugs and antispasmodics, but their standalone efficacy varies. This study evaluates the safety, tolerability, and efficacy of a fixed-dose combination (FDC) of camylofin dihydrochloride (50 mg) and diclofenac potassium (50 mg) in managing moderate-to-severe colic.

Objective: The objective of the study was to assess the safety, tolerability, and efficacy of camylofin-diclofenac FDC in adult patients with moderate-to-severe colic.

Methods: This open-label, multicentric, non-comparative, observational Phase IV study enrolled 200 adults with confirmed colic across four clinical sites. Participants received camylofin-diclofenac twice daily for 5 days. Primary endpoints included safety and tolerability assessments based on reported adverse events (AEs) and laboratory abnormalities. Secondary efficacy outcomes were evaluated using the clinical global impression scale, severity of illness scores, and efficacy index.

Results: Of the 200 participants, 191 completed the study. The most commonly reported AEs were mild gastritis (5%) and dizziness (2%), with no severe adverse effects recorded. Severity of illness scores significantly improved from baseline (4.23 ± 1.20) to day 3 (2.87 ± 0.86, $P < 0.0001$) and day 5 (1.65 ± 0.81, $P < 0.0001$). Global improvement and efficacy index scores also demonstrated significant reductions, supporting the FDC's effectiveness.

Conclusion: Camylofin-diclofenac FDC was well tolerated and effective in reducing colic severity. Its dual mechanism of smooth muscle relaxation and anti-inflammatory action makes it a promising therapeutic option for colic management.

Keywords: Antispasmodics, camylofin, colic pain management, diclofenac, fixed-dose combination therapy

Date of Submission: 28-01-2025
Date of Revision: 14-02-2025
Date of Acceptance: 07-03-2025

Access this article online
Website: http://innovationalpublishers.com/Journal/ijnmi
ISSN No: 2656-4656
DOI: 10.31690/ijnmi.2025.v010i01.002

Introduction

Colic is a significant clinical concern characterized by severe, spasmodic abdominal pain arising from conditions such as biliary, renal, or intestinal colic. Biliary colic results from gallstone obstruction, causing pain, nausea, and vomiting, while renal colic is associated with intense pain due to kidney stones.[1] Intestinal colic, often caused by blockages in the intestines, leads to nausea, vomiting, diarrhea, and abdominal

Address for Correspondence:
Archna Khurana, Department of Clinical Research, Texila American University, Module 310, III Floor, Tidel Park, Elcot-Sez, Aerodrome Post, Coimbatore - 641 014, Tamil Nadu, India. E-mail: archnakhurana193@gmail.com

cramping.[2] Although colic is commonly linked to infants, it also occurs in adults, presenting as recurrent episodes of pain that can last for weeks or even months.

The exact pathophysiology of colic varies depending on the underlying cause. Biliary colic arises from temporary obstruction of the cystic or common bile duct, leading to increased pressure and smooth muscle contractions. Renal colic occurs due to the movement of calculi through the urinary tract, triggering severe ureteral spasms.[3] Intestinal colic is caused by functional or mechanical obstructions, leading to dysmotility and increased intra-abdominal pressure. Epidemiological data suggest that gallstones affect approximately 10–20% of the global population, with biliary colic being one of the most frequent complications.[4] Similarly, renal colic accounts for a substantial number of emergency department visits worldwide, emphasizing the burden of this condition.[5]

The treatment of colic largely depends on its etiology, severity, and recurrence. Non-steroidal anti-inflammatory drugs (NSAIDs), such as diclofenac, are widely used as first-line therapy due to their anti-inflammatory and analgesic properties.[6] However, NSAIDs alone may not fully alleviate pain associated with smooth muscle spasms.[7] Antispasmodics, such as camylofin, provide direct smooth muscle relaxation, reducing colic episodes.[8] While opioids are occasionally used in severe cases, they carry risks of dependency and side effects, making them less favorable for routine use.[9]

Given the multifactorial nature of colic, combination therapy is increasingly recommended. Camylofin, a phosphodiesterase-IV inhibitor and antimuscarinic agent, directly relaxes smooth muscles, while diclofenac inhibits prostaglandin synthesis to reduce inflammation and pain.[10] This synergistic approach addresses both muscle spasms and inflammation, offering more effective pain relief compared to monotherapy. Fixed-dose combinations (FDCs) have been shown to improve treatment adherence and reduce the need for additional medications, further enhancing patient outcomes.[11]

The present study evaluates the efficacy, safety, and tolerability of a FDC of camylofin dihydrochloride (50 mg) and diclofenac potassium (50 mg) in the management of moderate-to-severe colic. This Phase IV, multicentric, non-comparative, observational clinical trial aims to determine whether this combination provides superior pain relief while minimizing adverse effects, thereby offering an effective and well-tolerated therapeutic option for colic management.

Objectives of the study

The aim of this prospective study is to assess a FDC of camylofin dihydrochloride (50 mg) and diclofenac potassium (50 mg) in terms of safety, tolerability, and efficacy.

Primary study objective

The primary objective of this trial is to evaluate the safety and tolerability of the FDC in the treatment of moderate-to-severe colic.

Secondary study objective

The secondary objective of this trial is to evaluate the efficacy of this FDC in the treatment of moderate-to-severe colic.

Materials and Methods

Study design

This was an open-label, multicentric, non-comparative, observational Phase IV clinical study assessing the safety, tolerability, and efficacy of a fixed-dose (50 mg) combination of camylofin dihydrochloride and diclofenac potassium in the treatment of moderate-to-severe colic. Patient baseline symptoms were used as indicators for assessing treatment effectiveness.

Study sites and ethical considerations

The study was registered on Clinical Trials Registry-India (CTRI) with the registration number CTRI/2019/05/018953. Ethical approvals were obtained from the respective Institutional Ethics Committees before study initiation. The study was conducted at the following four centers:

- Institute of Postgraduate Medical Education and Research, Kolkata
- Advance Critical Gillurkar Multispecialty Hospital, Nagpur
- King Georges Medical University, Lucknow
- Panchsheel Hospital, Delhi.

Informed consent was obtained from all subjects before any study-related procedures were performed. The study complied with applicable regulatory requirements, Indian Council of Medical Research's Ethical Guidelines, International Conference on Harmonization -Good Clinical Practice, and the Declaration of Helsinki. Subject confidentiality was maintained throughout the study using specific codes.

Study population

The study enrolled 200 adult patients (18–65 years) with symptoms of colic confirmed through clinical examination. A 20% dropout rate was anticipated, ensuring an evaluable population of at least 160 patients. Participants were enrolled based on the following inclusion and exclusion criteria:

Inclusion criteria

- Adults aged 18–65 years
- Written informed consent obtained
- At least 6 months history of a confirmed diagnosis of colic.

Exclusion criteria

- Pregnancy or lactation
- Hypersensitivity to camylofin or diclofenac
- History of serious cardiovascular, renal, hepatic, or neurological disorders
- Prostatic hypertrophy, glaucoma, mechanical stenosis, paralytic ileus
- Participation in another clinical trial within the last 3 months.

Study procedures

Each subject visited the study center at least 3 times:

Visit 1 (day 0 - screening and enrollment)

- Informed consent obtained
- Demographic details recorded
- Medical history and physical examination conducted
- Baseline laboratory tests performed
- Subjects meeting inclusion criteria enrolled and provided study medication.

Visit 2 (day 3 – follow-up assessment)

- Assessment of vitals and physical condition
- Adverse event (AE) monitoring
- Treatment compliance check.

Visit 3 (day 5 – final assessment)

- Final vitals, laboratory tests, and AE monitoring
- Collection of patient diary cards
- Final treatment compliance check.

Study drug administration and accountability

- Subjects received one tablet (camylofin 50 mg + diclofenac 50 mg) twice daily for 4 days
- Study medication was stored at 25°C ± 5°C under restricted access
- Used and unused medication strips were returned for accountability.

Study assessments

Primary efficacy parameters

- Change in severity of illness from baseline (day 0) to end of study (day 5)
- Change in global impression scores from day 3 to day 5
- Change in efficacy index from day 3 to day 5.

Safety and tolerability assessments

- Laboratory-related AEs (baseline vs. day 5)
- Subject self-reported AEs.

AE monitoring and reporting

- AEs were documented with details on onset, duration, intensity, and causal relationship to study medication. Serious AEs (SAEs) were reported immediately, with full documentation submitted within 14 days. SAEs included:
- Death
- Life-threatening conditions
- Hospitalization or prolonged hospital stay
- Significant disability or incapacity.

Study discontinuation and protocol compliance

Subjects could withdraw at any time or be removed due to non-compliance, safety concerns, or AEs. Any deviations from protocol were documented and reported.

Statistical analysis

Data analysis was performed using Statistical Package for the Social Sciences-personal computer version 8.0. Continuous variables were presented as mean ± standard deviation, while categorical variables were expressed as percentages. The analysis was conducted based on the intention-to-treat principle. Categorical data were assessed using the Chi-square (χ^2) test or Fisher's exact test when cell counts were ≤5. For the primary efficacy parameters, a paired *t*-test was used to compare changes in clinical variables from baseline (day 0) to follow-up visits (day 3 and day 5). A $P = <0.05$ was considered statistically significant. The safety population included all subjects who received at least one dose of the study drug and had post-dose safety data available.

Flow chart of the study

The study was conducted following a structured process, as outlined in the study flow chart [Figure 1]. This flowchart illustrates the participant selection, intervention phases, and assessment points, ensuring clarity in the research methodology.

Results

Demographic characteristics

A total number of 200 individuals were enrolled in the study out of which 123 were men and 76 were women, with ages ranging from 18 to 63 years (median 37.23). Among all 200 subjects, nine subjects dropped out, and the remaining 191 were evaluated for study outcomes [Table 1]. The highest proportion (33.0%) of subjects were younger than 30 years followed by 27.0% in the age range of 30–40 years, 22.0% in 41–50 years, and 14.5% in 51–60 years [Table 2]. Only 3.5% of subjects had an age >60 years.

Primary objective: Evaluation of safety and tolerability of the FDC in the treatment of moderate-to-severe colic

The safety and tolerability of the FDC in the treatment of moderate-to-severe colic were evaluated based on the subject's self-reported AEs and laboratory abnormalities (if any) on day

Table 1: Number and percentage of study subjects

Gender	Frequency (percentage)
Men	77 (38.5)
Women	123 (61.5)

Table 2: Descriptive statistics of different ages of study subjects

Age in years	Frequency	Percentage
<30	66	33.0
30–40	54	27.0
41–50	44	22.0
51–60	29	14.5
>60	07	3.5
Mean±SD (Min, Max)	29.52±5.36 (18, 65)	

5. A total of 10 (5%) subjects reported different types of AEs [Table 3]. Out of all subjects who reported AEs, 04 (40.0%) had gastritis, 01 (10.0%) had vomiting, 01 (10.0%) had nausea, 02 (20.0%) had dizziness, 01 (10.0%) had fever with rigor and 01 (10.0%) had headache. None of the subject's reported AEs were assessed by the investigator as related to the drug (given orally) and graded as mild in occurrence. There were no AE (s) recorded in the study related to laboratory abnormalities.

Secondary objective: Evaluation of efficacy of the product by clinical global impression (CGI) scale

Changes in the severity of illness from visit 1 (day 0) to visit 2 (day 3) and visit 3 (day 5)

The severity of illness was 4.23 ± 1.20 at visit 1 (day 0) which decreased significantly to 2.87 ± 0.86 at the next visit, that is, visit 2 (day 3) ($P < 0.0001$) and further to 1.65 ± 0.81 at visit 3 (day 5) ($P < 0.0001$) [Table 4]. The change in the severity of illness from visit 1 to visit 2 was −32.15% (1.36 ± 0.34) which was increased to −60.99% from visit 1 to visit 3 (2.63 ± 0.39) [Table 5].

Changes in the global improvement during visit 2 (day 3) to visit 3 (day 5)

The global improvement was 2.85 ± 0.78 at visit 2 which decreased significantly during visit 3 [1.71 ± 0.75, $P < 0.0001$, Table 6]. A negative shift of global improvement denotes the positive effect of the study drug on 7 7-point scale, 7 being very much worse and 1 being very much improved [Table 7].

Change in efficacy index from visit 2 (day 3) to visit 3 (day 5)

The efficacy index was evaluated for a score of 0 (marked improvement and no side effects) to a score of 4 (unchanged or worse and side effects outweigh the therapeutic effects). The efficacy index was 1.45 ± 0.89 at visit 2 (day 3) which significantly decreased to 1.05 ± 0.88 at visit 3 (day 5) [$P < 0.0002$, Table 8]. A negative shift of the efficacy index from visit 2 (day 3) to visit 3 (day 5) denotes the positive efficacy effect of the study product [Table 9].

Discussion

Pain management in colic remains a clinical challenge, necessitating an effective and well-tolerated therapeutic approach. While NSAIDs are recommended as first-line agents for renal colic by the European Association of Urology guidelines, the choice of specific NSAIDs and their administration methods are not clearly defined. Given concerns regarding NSAID-related adverse effects, opioids are often used as rescue therapy despite their well-documented risks

Table 3: Summary of subject-reported adverse events

No.	Event type	Outcome	Generic name of the drug (s)	Class of drug
1	Vomiting	Resolved	Ondansetron	Serotonin (5HT3) Antagonist
4	Gastritis	Resolved	Pantoprazole and domperidone	Proton pump inhibitor and propulsive
2	Dizziness	Resolved	Prochlorperazine	Antipsychotic
1	Fever with rigor	Resolved	Paracetamol	Analgesic and antipyretic
1	Nausea	Resolved	Ondansetron	Serotonin (5HT3) antagonist
1	Gastritis	Resolved	Pantoprazole	Proton pump inhibitor
1	Dizziness	Resolved	Prochlorperazine	Antipsychotic
1	Gastritis	Resolved	Rabeprazole and levosulpiride	Proton pump inhibitor and benzamide
1	Gastritis	Resolved	Activated dimethicone, magnesium hydroxide, aluminum hydroxide and sorbitol solution	Magnesium compounds, aluminum compounds and osmotic laxative
1	Headache	Resolved	Paracetamol	Analgesic and antipyretic

N: No. of subjects in which adverse events were reports

Table 4: Severity of illness at each visit

Variables	N	Mean	SD	Median	(Min, Max)
Severity of illness at visit 1	188	4.23	1.2	4	(2, 7)
Severity of illness at visit 2	188	2.87	0.86	3	(1, 5)
Severity of illness at visit 3	188	1.65	0.81	2	(0, 4)

Table 5: Mean percent change in severity of illness from visit 1 to visit 2 and 3

Parameter	Statistics *n*	Value 188	P-value	95% CI for mean change	Percent change in severity of illness (%)
Change in severity of illness from visit 1 to visit 2 (day 0 to day 3)	Mean (SD)	−1.4 (1.15)	<0.0001*	(−1.20; −1.53)	−32.15
	Median	−1			
	Min; Max	−5, 0			
Change in severity of illness from visit 1 to visit 3 (day 0 to day 5)	Mean (SD)	−2.6 (1.43)	<0.0001*	(−2.38; −2.79)	−60.99
	Median	−2			
	Min; Max	−7, 0			

CI: Confidence interval, *P-value was evaluated by using a paired t-test

Table 6: Global improvement during visit 2 and 3

Variables	*n*	Mean	SD	Median	(Min, Max)
Global improvement at visit 2	188	2.85	0.78	3	(0, 5)
Global improvement at visit 3	188	1.71	0.75	2	(0, 4)

Table 7: Mean change in global improvement from visit 2 to visit 3

Parameter	Statistics	Value	*P*-value	95% CI for mean change
Change in global improvement from visit 2 (day 3) to visit 3 (day 5)	*n* Mean (SD) Median Min; Max	188 −1.1 (0.88) −1 −3, 1	<0.0001*	(−1.26; −1.01)

CI: Confidence interval, **P*-value was evaluated by using a paired *t*-test

Table 8: Efficacy index during visits 2 and 3

Variables	*n*	Mean	SD	Median	(Min, Max)
Efficacy index at visit 2	188	1.45	0.89	1.25	(0.25, 3.75)
Efficacy index at visit 3	188	1.05	0.88	1.25	(0.25, 3.25)

Table 9: Mean change in efficacy index from visit 2 to visit 3

Parameter	Statistics	Value	*P*-value	95% CI for mean change
Change in Efficacy Index From visit 2 (day 3) to visit 3 (day 5)	N Mean (SD) Median Min; Max	188 −0.4 (0.7) −0.25 −2.5, 3	<0.0001*	(−0.29; −0.50)

CI: Confidence interval, **P*-value was evaluated by using a paired *t*-test

of dependency and gastrointestinal side effects. A study by Guichard *et al*.[10] highlighted that opioids, although effective, are associated with higher incidences of AEs, particularly nausea and respiratory depression. Our study aimed to assess the efficacy and safety of a FDC of camylofin and diclofenac for the treatment of moderate-to-severe colic and demonstrated significant pain reduction with a favorable safety profile.

NSAIDs like diclofenac sodium are commonly used for analgesia in colic pain, particularly in the Indian clinical setting. However, NSAIDs alone have limitations, with reported failure rates requiring rescue therapy in 7–39% of cases. A study by Vashist *et al*.[12] reported that despite being effective, NSAIDs often necessitate adjunctive therapy in severe cases. In addition, their use is contraindicated in specific populations, including pregnant women and individuals with gastrointestinal disorders, as described by Murthy *et al*.[9] and Sivaprasad *et al*.[13] The use of antispasmodics in colic management is well documented, but traditional anticholinergic agents require high doses, leading to transient efficacy and increased side effects, as noted by Wild *et al*.[14] camylofin, a dual-action smooth muscle relaxant with anticholinergic and phosphodiesterase-IV inhibitory properties, has been widely used for decades in India and has demonstrated superior spasmolytic potency compared to other antispasmodics. A study by Mayadeo[8] confirmed the superior efficacy of camylofin over drotaverine and hyoscine in managing colic pain.

Our findings align with previous studies that have highlighted the effectiveness of camylofin in colic management. A study by Mayadeo[8] compared camylofin with other antispasmodics and found it to be superior in efficacy and tolerability. Furthermore, the combination of camylofin with NSAIDs has been shown to enhance pain relief in colic-related conditions, providing both smooth muscle relaxation and anti-inflammatory benefits. A study by Stein *et al*. demonstrated that diclofenac provides comparable analgesic effects to ketorolac in renal colic treatment, with significant pain reduction observed within 60–120 min of administration.[7] In addition, a randomized controlled trial by Akriviadis *et al*. confirmed the superior efficacy of diclofenac over placebo in the treatment of colic pain.[15] Similarly, Kumar *et al*.[16] and Dash *et al*.[17] conducted trials comparing diclofenac with other analgesics and found it to be significantly more effective in achieving rapid pain relief.

In our study, the combination of camylofin and diclofenac led to a significant reduction in severity of illness from baseline to day 5, with a 60.99% decrease in symptoms. These findings are consistent with prior studies that have demonstrated the benefits of combination therapy in colic management. A meta-analysis by Gu *et al*.[18] evaluating NSAID use in acute renal colic, including 65 randomized controlled trials with over 8,600 participants, concluded that NSAIDs were superior to opioids, paracetamol, and combination therapy alone but suggested that combination therapy may be beneficial for patients with uncontrolled pain. A systematic review by García-Perdomo *et al*.[19] further found that diclofenac provided superior pain relief compared to other NSAIDs, reinforcing our study's results that indicate a FDC of camylofin and diclofenac effectively reduces colic pain while maintaining a favorable safety profile.

Although our study did not directly compare the combination therapy to monotherapy regimens, the observed reduction in CGI scores and improvement in efficacy index suggests a strong therapeutic benefit. The tolerability of the combination therapy was also confirmed, with only 5% of subjects reporting mild AEs such as gastritis and dizziness. Importantly, no laboratory-related AEs were observed, reinforcing the safety of the FDC. A study by Phillips *et al*.[20] and Golzari *et al*.[21] reported similar findings, indicating minimal adverse effects with camylofin and diclofenac use in colic treatment.

The clinical implications of our study suggest that a FDC of camylofin and diclofenac is an effective therapeutic option for moderate-to-severe colic, offering rapid pain relief with a favorable safety profile. While further comparative trials with other NSAIDs and analgesic combinations would provide additional insights, our results support the integration of this combination into routine clinical practice. Given the historical success of camylofin in colic pain

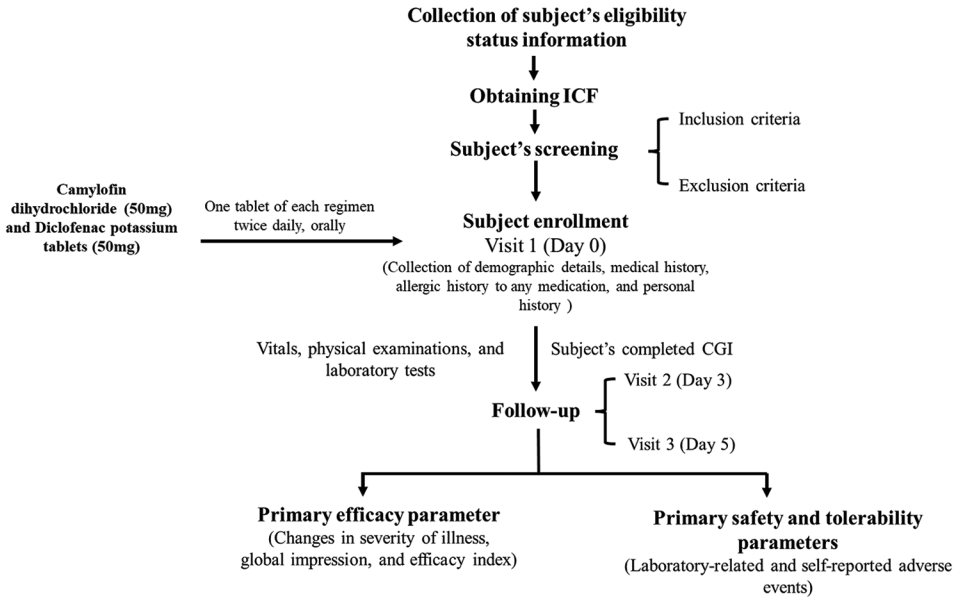

Figure 1: Study flow chart

management and the established efficacy of diclofenac, this combination presents a promising alternative to traditional monotherapies.

Conclusion

Camylofin-diclofenac FDC is an effective and well-tolerated treatment for moderate-to-severe colic. Its dual-action mechanism enhances pain relief and symptom resolution compared to monotherapy. Future studies should explore its long-term efficacy and comparative effectiveness against alternative combination therapies.

Acknowledgment

Na.

Funding

None.

Conflicts of Interest

None.

References

1. Baiu I, Hawn MT. Gallstones and biliary colic. JAMA 2018;320:1612.
2. Motov S, Drapkin J, Butt M, Thorson A, Likourezos A, Flom P, *et al*. Analgesic administration for patients with renal colic in the emergency department before and after implementation of an opioid reduction initiative. West J Emerg Med 2018;19:1028-35.
3. Kominsky HD, Rose J, Lehman A, Palettas M, Posid T, Caterino JM, *et al*. Trends in acute pain management for renal colic in the emergency department at a tertiary care academic medical center. J Endourol 2020;34:1195-202.
4. Cervellin G, Mora R, Ticinesi A, Meschi T, Comelli I, Catena F, *et al*. Epidemiology and outcomes of acute abdominal pain in a large urban emergency department: Retrospective analysis of 5,340 cases. Ann Transl Med 2016;4:362.
5. Zhu J, Cao Y, Yu M, Liu C, He W, Zeng B, *et al*. Efficacy and safety of combination therapy with drotaverine and ketorolac versus ketorolac monotherapy for acute renal colic: A retrospective study of 322 patients. Int J Clin Exp Med 2017;10:3454-61.
6. Safdar B, Degutis LC, Landry K, Vedere SR, Moscovitz HC, D'Onofrio G. Intravenous morphine plus ketorolac is superior to either drug alone for treatment of acute renal colic. Ann Emerg Med 2006;48:173-81.
7. Stein A, Ben Dov D, Finkel B, Mecz Y, Kitzes R, Lurie A. Single-dose intramuscular ketorolac versus diclofenac for pain management in renal colic. Am J Emerg Med 1996;14:385-7.
8. Mayadeo N. Camylofin dihydrochloride injection: A drug monograph review. Int J Reprod Contracept Obstet Gynecol 2019;8:359-67.
9. Murthy GV, Gupta SK, Bachani D, Jose R, John N. Current estimates of blindness in India. Br J Ophthalmol 2005;89:257-60.
10. Guichard G, Fromajoux C, Cellarier D, Loock PY, Chabannes E, Bernardini S, *et al*. Prise en charge de la colique néphrétique chez la femme enceinte: À propos de 48 cas [Management of renal colic in pregnant women, based on a series of 48 cases]. Prog Urol 2008;18:29-34.
11. Boblewska J, Dybowski B. Methodology and findings of randomized clinical trials on pharmacologic and non-pharmacologic interventions to treat renal colic pain - a review. Cent Eur J Urol 2023;76:212-26.
12. Vashist P, Singh S, Gupta N, Saxena R. Role of early screening for diabetic retinopathy in subjects with diabetes mellitus: An overview. Indian J Community Med 2011;36:247-52.
13. Sivaprasad S, Gupta B, Crosby-Nwaobi R, Evans J. Prevalence of diabetic retinopathy in various ethnic groups: A worldwide perspective. Surv Ophthalmol 2012;57:347-70.
14. Wild S, Roglic G, Green A, Sicree R, King H. Global prevalence of diabetes: Estimates for the year 2000 and projections for 2030. Diabetes Care 2004;27:1047-53.
15. Akriviadis EA, Hatzigavriel M, Kapnias D, Kirimlidis J, Markantas A, Garyfallos A. Treatment of biliary colic with diclofenac: A randomized, double-blind, placebo-controlled study. Gastroenterology 1997;113:225-31.
16. Kumar A, Deed JS, Bhasin B, Kumar A, Thomas S. Comparison of the effect of diclofenac with hyoscine-N-butylbromide in the symptomatic treatment of acute biliary colic. ANZ J Surg 2004;74:573-6.
17. Dash A, Maiti R, Bandakkanavar TK, Arora P. Intramuscular drotaverine and diclofenac in acute renal colic: A comparative study of analgesic efficacy and safety. Pain Med 2012;13:466-71.
18. Gu HY, Luo J, Wu JY, Yao QS, Niu YM, Zhang C. Increasing nonsteroidal

anti-inflammatory drugs and reducing opioids or paracetamol in the management of acute renal colic: Based on three-stage study design of network meta-analysis of randomized controlled trials. Front Pharmacol 2019;10:96.
19. García-Perdomo HA, Echeverría-García F, López H, Fernández N, Manzano-Nunez R. Pharmacologic interventions to treat renal colic pain in acute stone episodes: Systematic review and meta-analysis. Prog Urol 2017;27:654-5.
20. Phillips E, Hinck B, Pedro R, Makhlouf A, Kriedberg C, Hendlin K, *et al*. Celecoxib in the management of acute renal colic: A randomized controlled clinical trial. Urology 2009;74:994-9.
21. Golzari SE, Soleimanpour H, Rahmani F, Zamani Mehr N, Safari S, Heshmat Y, *et al*. Therapeutic approaches for renal colic in the emergency department: A review article. Anesth Pain Med 2014;4:e16222.

How to cite this article: How to cite this article: Kumar D, Khurana A. Efficacy, Safety, and Tolerability of a Fixed-Dose Combination of Camylofin and Diclofenac in the Management of Moderate-to-Severe Colic: A Phase IV Clinical Study. Int J Nurs Med Invest. 2025;10(1):8-14.