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Original Research Article

Camylofin 50 mg and Paracetamol 325 mg in patients with acute colicky abdominal pain: a prospective and open-label study

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ABSTRACT

Background: Acute colicky abdominal pain (AP), resulting from the sudden spasm of hollow viscera, is frequently managed with a combination of analgesics and antispasmodics. Camylofin is an anti-spasmodic medication whereas paracetamol is a widely prescribed analgesic and antipyretic for managing mild-to-moderate pain. This study evaluates the effectiveness of a fixed-dose combination (FDC) of camylofin 50 mg and Paracetamol 325 mg in alleviating acute colicky abdominal pain.
Methods: In this prospective, single-arm, open-label study, 100 female patients aged 18-65 with acute colicky abdominal pain were administered one tablet thrice daily for 3-5 days of camylofin 50 mg and paracetamol 325 mg daily for 3-5 days. Pain intensity was assessed using the visual analog scale (VAS) at baseline, Day 3 and Day 5.
Results: A significant reduction was observed in the mean VAS scores from baseline (77.8) to Day 5 (4.0) ($p<0.001$). At day 5, 83.0% of patients reported no pain, with minimal adverse events (2% fever and 1% headache with fever). There was a significant change (-27.5) in mean pain intensity VAS score before (77.8) and after (50.2) medication, $p<0.001$. The percentage change in the mean pain intensity based on VAS score was highest in subjects with urinary AP (97.4%), followed by menstrual AP (94.9%) and unexplained AP (94.5%).
Conclusions: The FDC of camylofin 50 mg and Paracetamol 325 mg is significantly effective in managing acute colicky abdominal pain, providing rapid and substantial pain relief with minimal adverse events.

Keywords: Abdominal colic, Camylofin, Paracetamol

INTRODUCTION

Abdominal colic is an intense abdominal pain, often localized to multiple hollow viscera, which typically escalates, peaks and then gradually subsides. Colicky pain is typically triggered by the sudden spasm of the tubular structure and can be biliary, intestinal or ureteric in origin.[1-4] The current management of colicky abdominal pain (AP) consist of analgesics, antispasmodics, followed by antibiotics.[5] Changes in gastrointestinal motility and visceral sensation often contribute to abdominal pain. In these cases, antispasmodics function as smooth muscle relaxants or antagonists, inhibiting excitatory neuromuscular neurotransmission to ensure pain relief.[6-8] Pain is a subjective sensation that is important to evaluate in a clinical setting.[8,9] Pain score thus becomes crucial in defining diagnosis and eventually holds a key spot in administration of treatment. The Numeric rating scale (NRS-11) and visual analog scale (VAS) are among the few validated scales that are used to assess the pain.[10,11] Use of VAS score to assess effectiveness outcomes in the current study ensured robustness of findings by 2 independent measures.[12]

Camylofin is an anti-spasmodic medication that effectively alleviates colicky pain through its dual mechanisms: musculotropic and neurotropic effects, which contribute to smooth muscle relaxation.[3] For the past 50 years, camylofin dihydrochloride, known for its strong antispasmodic properties, has been used in clinical

practice.[13] Used in clinical practice for over 50 years, camylofin dihydrochloride is known for its strong antispasmodic properties. It provides a direct spasmolytic effect on smooth muscles similar to papaverine and exhibits a mild anticholinergic effect akin to atropine.[14] This anticholinergic action blocks muscarinic type-3 receptors in the smooth muscle cells of the colon, reducing motility and alleviating colicky pain caused by excessive contractions and spasms in hollow viscera such as the intestines and ureters.[1,2]

In addition to this, it inhibits the enzyme phosphodiesterase IV, which leads to higher levels of cyclic AMP inside the cells and subsequently relaxes smooth muscles by reducing intracellular calcium levels.[3]

In contrast, paracetamol (acetaminophen) is a widely prescribed analgesic and antipyretic for managing fever and mild-to-moderate pain in people of all ages. While there is limited evidence on its effectiveness for treating abdominal colicky pain in children, clinical studies suggest that combining an antispasmodic like hyoscine or camylofin with paracetamol can be effective in managing abdominal pain.[15,16]

Fixed-dose combination (FDC) drugs offer several benefits, including synergistic effects, improved tolerability, complementary mechanisms of action and cost-effectiveness. However, their safety must be confirmed in real-world settings.[17] With robust clinical trial data available for Indian women, camylofin and its combinations are well-regarded by obstetricians and gynecologists.

They represent a valuable option in the treatment protocols for abdominal spasmodic pain and labor augmentation.[3] In light of the aforementioned literature, the current study aims to evaluate the effectiveness of the fixed-dose combination (FDC) of 50 mg camylofin and 325 mg paracetamol on pain intensity in patients with acute colicky abdominal pain.

METHODS

Study design

This was a prospective, single-arm, open-labelled study involving patients with acute colicky abdominal pain for 3 or 5 days, conducted at Krishna Medical center, Lucknow, from January 2024 to June 2024. A written consent form was obtained from all the enrolled patients.

Inclusion criteria

Female patients in the age group of 18-65 years, attending OPD with acute colicky abdominal pain and having at least one episode of colicky pain with 24 hours prior to visit and non-complicated cases of acute colicky abdominal pain confirmed by ultrasonography (USG), performed prior to the treatment initiation were included in this study.

Exclusion criteria

The patients with history of hypersensitivity to the study drug, undergone coronary bypass graft surgery, history of epilepsy, inflammatory bowel disease, chronic abdominal pain including celiac disease, lactose intolerance, ulcerative colitis and Crohn's disease, diagnosed with narrow angle glaucoma, mechanical stenosis, urinary retention, mega colon, GI hemorrhage, tachyarrhythmia and porphyria. Pregnant and lactating women were excluded from the study.

Study method

The enrolled patients were administered with one tablet thrice a day for 3 or 5 days of camylofin 50 mg and paracetamol 325 mg for 3-5 days. Patients were screened on Day 1, Day 3 and Day 5 (Figure 1). Screening assessments included medical history, a complete physical examination, vital signs measurement, VAS severity scale for pain and a urine pregnancy test.

Endpoints

The primary endpoint of this study was to assess the effectiveness of the FDC of camylofin 50 mg and paracetamol 325 mg on pain intensity in patients with acute colicky abdominal pain.

The secondary endpoint of the study was to evaluate the onset of action of the FDC of camylofin 50 mg and paracetamol 325 mg in the patients with acute colicky abdominal pain.

Ethical considerations

This study was conducted in accordance with the protocol and consensus ethical principles derived from international guidelines including the Declaration of Helsinki, AYUSH

Guidelines, applicable ICH GCP Guidelines, New Drugs and Clinical Trial Rules 2019 and other applicable laws and regulations. The Study was registered under Clinical Trial registry of India (CTRI) before enrolment of First Subject (CTRI/2024/01/061405).

Statistical analysis

All the statistical analysis was performed in SPSS software, version 21. The descriptive data was given in n %), while the quantitative data was given in mean (SD). A p-value of<0.050 was considered as statistically significant.

RESULTS

Demographic characteristics of the patients

A total of 100 patients were included in this study. The mean age of the patients was 30.3 years, with a mean

height of 156.0 cm and a mean weight of 59.4 kg. The mean BMI of the patients was 24.4 kg/m^2. The mean onset of pain was 13.7 hours.

The mean duration of onset of action of drugs was 44.8 mins. Around 56.0% of patients had menstrual abdominal pain, followed by unexplained abdominal pain (37.0%). This is summarized in Table 1.

Treatment compliance

The treatment compliance was 100.0% throughout the study.

Vital signs

The systolic blood pressure, diastolic blood pressure and pulse rate were within normal ranges. There was a significant increase in mean respiration rate from baseline (16.7) to day 3 (17.8) and day 5 (18.5), p<0.001. This is summarized in Table 2.

VAS score severity

At baseline, the majority of patients (83.0%) had severe VAS score severity (61-100). However, at day 3, the majority of patients (49.0%) had moderate VAS score severity (31-60) and at day 5, the majority of patients (83.0%) had no pain. This is summarized in Table 3.

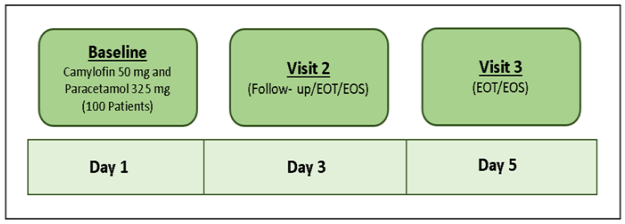

Figure 1: Overview of the study.
EOS, end of study; EOT, end of treatment.

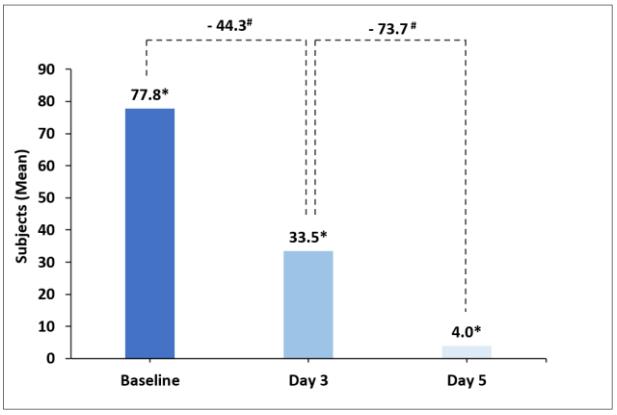

Figure 2: Mean improvement in VAS score from baseline to day 5 follow-up.
*Significant p-value <0.005, # Change in mean difference between baseline, Day 3 and Day 5/EOS.

Mean improvement in VAS score from baseline to Day 5 follow-up

A significant reduction in the mean VAS score was observed from baseline (77.8) to day 3 (33.5). The mean difference from baseline to day 3 (-44.3) was statistically significant (p<0.001). Similarly, significant difference (-73.7) in mean VAS score was observed from baseline (77.8) to day 5 (4.0), p<0.001. This is summarized in Figure 2. There was a significant change (-27.5) in mean pain intensity VAS score before (77.8) and after (50.2) medication, p<0.001 (Figure 3).

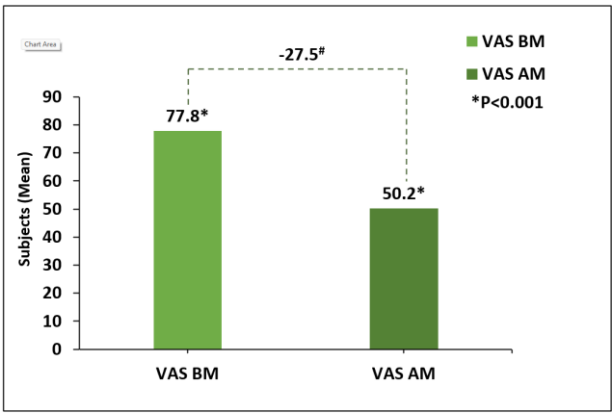

Figure 3: Pain intensity VAS score before and after medication.
*Significant p value<0.005, #Change in mean difference between baseline, Day 3 and Day 5/EOS, VAS BM, Visual Analogue Scale before medication; VAS AM, Visual Analogue Scale after medication.

Comparing mean VAS scores by subgroups

Upon comparing the subgroups from baseline to EOS, the mean VAS scores were reduced the most in urinary AP group (81.4 vs. 2.1), followed by menstrual AP (77.2 vs. 3.9) and unexplained AP (78.0 vs. 4.6). This is summarized in Figure 4.

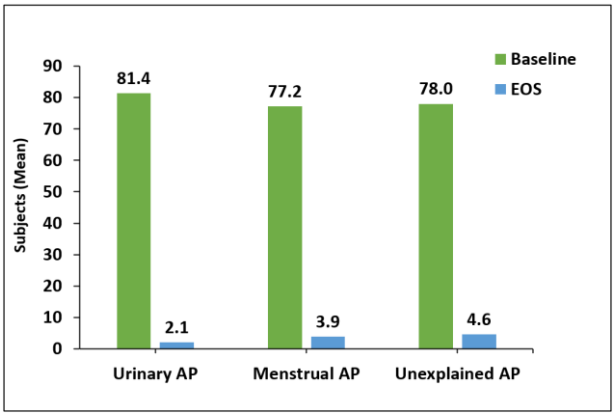

Figure 4: Comparing Mean VAS scores by subgroups.
AP: abdominal pain; VAS: Visual analogue scale.

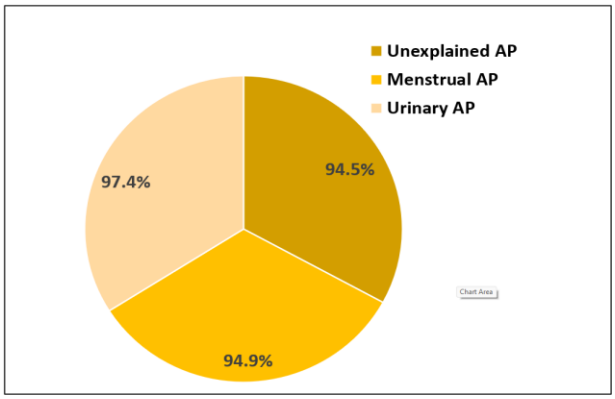

Figure 5: Percentage change in the mean pain intensity based on VAS score.

AP, abdominal pain

Percentage change in the mean pain intensity based on VAS score

The percentage change in the mean pain intensity based on VAS score was highest in subjects with urinary AP (97.4%), followed by menstrual AP (94.9%) and unexplained AP (94.5%). This data is summarized in Figure 5.

Adverse events

Among all the patients, only three patients reported adverse events (AEs); at day 3, 2.0% of the patients reported fever while at day 5, only 1.09% reported headache with fever. This is summarized in Figure 3.

Table 1: Demographic characteristics of patients (n=100).

Parameter	Number of patients
Age (years)	30.3 (8.3)
Height (cm)	156 (3.2)
Weight (kg)	59.4 (10.2)
BMI (kg/m^2)	24.4 (4.1)
Onset pain (hours)	13.7 (5.5)
Onset of action of drugs (min)	44.8 (10.2)
Medical history, N (%)	
Menstrual AP	56 (56.0)
Unexplained AP	37 (37.0)
Urinary AP	7 (7.0)

Data given as mean (SD), otherwise specified, AP, abdominal pain; BMI, body mass index

Table 2: Change in vital signs from baseline to EOS/Day 5.

Parameter	Visits	Number of patients	Change from baseline	P value
Systolic blood pressure (SBP), mmHg	Baseline	119.8 (13.7)	-	-
	Day 3	118.5 (10.7)	-1.38	0.090
	EOS	119.2 (11.1)	-0.68	0.438
Diastolic blood pressure (DBP), mmHg	Baseline	75.4 (9.5)	-	-
	Day 3	75.7 (8.0)	0.28	0.754
	EOS	74.8 (7.2)	-0.58	0.558
Pulse rate (bpm)	Baseline	76.9 (10.9)	-	-
	Day 3	77.5 (8.1)	0.62	0.488
	EOS	79.0 (7.4)	2.08	0.034
Respiration rate (bpm)	Baseline	16.7 (1.3)	-	-
	Day 3	17.8 (1.3)	1.07	<0.001*
	EOS	18.5 (1.5)	1.76	<0.001*
Temperature (ºC)	Baseline	36.0 (0.7)	-	-
	Day 3	36.1 (0.8)	0.03	0.719
	EOS	36.1 (0.6)	0.05	0.556

Data is given as mean (SD). *Significant p-value<0.005

Table 3: VAS score severity.

VAS severity	Baseline (n=100)	Day 3 (n=100)	Day 5 (n=100)
None	0	9 (9.0)	83 (83.0)
Mild (1-30)	0	40 (40.0)	11 (11.0)
Moderate (31-60)	17 (17.0)	49 (49.0)	6 (6.0)
Severe (61-100)	83 (83.0)	2 (2.0)	0

DISCUSSION

The present study investigates a FDC of camylofin and Paracetamol, which integrates an antispasmodic and an analgesic to target acute colicky abdominal pain. While both drugs are established individually, their combined use for this specific pain type and in this formulation may offer new insights into optimizing treatment. This study offers multiple key insights like high compliance, significant pain reduction and minimal AEs. Also, it highlights the FDC's high effectiveness in reducing pain across various types of AP, with substantial and statistically significant reductions in VAS scores.

As a key determinant of effectiveness, there was a significant reduction ($p<0.0001$) in pain intensity, as measured by the VAS scale, after 5 days of treatment. The mean VAS score for urinary pain decreased from 81.4 to 2.1, menstrual pain decreased from 77.2 to 3.9 and unexplained pain decreased from 78.0 to 4.6 by Day 5. These results were similar to another study by Nagendra et al, where a substantial majority of patients (95.1% of the 185 patients in the study cohort) experienced a reduction in pain from baseline.[17] In this study, an oral fixed-dose combination (FDC) of camylofin 25 mg and paracetamol 300 mg led to significantly greater reductions in VAS pain scores compared to an FDC of dicyclomine 20 mg and paracetamol 500 mg, after 5 days of treatment.

Although the existing literature extensively supports the effectiveness of camylofin in obstetric settings, there are comparatively few studies on its efficacy for treating abdominal colic. Camylofin works through a dual mechanism; it relaxes smooth muscle cells by selective inhibition of the enzyme phosphodiesterase IV, which boosts cyclic AMP levels and it also has a mild atropine-like anticholinergic effect, enhancing its antispasmodic properties.[3]

This is further reinforced by the fact that the percentage change in pain intensity was reported in urinary AP (97.4%), menstrual (94.9%) as well as unexplained pain (94.5%). A study conducted in India on patients with intestinal, renal and biliary colic found that 25 mg of camylofin provided effective pain relief in over 94% of participants.[14]

Another important or indicator of significant study is aspect of any study AEs were rare and generally mild, indicating good tolerability of the FDC, as 3 (3.2%) of patients reported 2 (2.0) fever and only 1 (1.0%) of patients reported headache and fever. In another study by Pandey et al, only 3 patients (2.1% of the total) reported one AE each, all of which were linked to the study drug but were resolved without lasting effects.[12]

The FDCs provide benefits by improving therapeutic outcomes for patients who don't respond well to single-drug therapy. By combining multiple drugs, FDCs harness their synergistic or additive effects to deliver significant therapeutic advantages and rapid results, often using lower doses of each drug.[18] These results highlight the effectiveness of the camylofin and Paracetamol FDC in rapidly reducing pain intensity and improving overall patient comfort in a real-world setting.

Use of Visual Analog Scale (VAS) for pain assessment ensures robustness and reliability in measuring pain intensity and treatment efficacy. The study includes monitoring of vital signs throughout the study period, providing a comprehensive view of the treatment's impact on physiological parameters. The study is conducted in a real-world setting with patients presenting with acute colicky abdominal pain, potentially filling a gap in clinical practice where FDCs have not been extensively studied in this context.

This study bears some limitations like its study design was a single-arm design which lacks a control group, which limits the ability to compare the FDC's effectiveness against other standard treatments or placebo. Another concern is the short duration of the study, the study only spans 3 or 5 days, which may not capture long-term efficacy or safety of the FDC. Furthermore, the study was limited to female patients with specific inclusion criteria, which may not be representative of the general population with abdominal pain.

Further studies with randomized, controlled design to compare the FDC against placebo or other standard treatments can provide a clear picture of camylofin and paracetamol relative efficacy. Exploring the specific mechanisms by which camylofin and Paracetamol interact to provide relief, including their combined effects on different types of colicky pain can help further. A larger sample size and longer follow-up could provide a more comprehensive assessment of potential adverse effects and interactions with other medications.

CONCLUSION

This study has successfully demonstrated the effectiveness of the FDC of camylofin 50 mg and Paracetamol 325 mg in managing acute colicky abdominal pain. The combination therapy led to a significant reduction in pain intensity, with reduction in the mean VAS score by Day 5. This substantial decrease highlights the efficacy of the FDC in providing rapid and effective relief for patients suffering from acute colicky pain.

Additionally, the FDC demonstrated a favourable safety profile, with AEs being rare, mild and transient, thereby highlighting its tolerability. Future research, including randomized controlled trials and additional studies with larger sample sizes and extended follow up periods, are recommended to further validate these findings and assess the efficacy of this treatment approach. Overall, this study contributes valuable insights into optimizing the management of acute colicky abdominal pain, reinforcing the potential of FDC therapy in clinical practice.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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