

Effect of Inhaled Salbutamol on Pain Severity in Patients Presenting with Acute Renal Colic: A Double-Blind Randomized Clinical Trial

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Abstract

Article history:

Received: 21 Sep 2025
Accepted: 10 Oct 2025
Available online: 15 Oct 2025

Keywords:

Renal colic
Salbutamol
Acute pain
Emergency medicine
Clinical trial
VAS

Background: Renal colic is a common and severely painful emergency condition often caused by ureteral stones. Rapid pain management is critical. This study evaluates the efficacy of inhaled salbutamol, a β_2 -agonist with smooth muscle relaxant properties, as an adjunct therapy in reducing pain severity in patients with acute renal colic.

Methods: In this double-blind randomized controlled trial, 204 patients with moderate renal colic pain (based on the Visual Analog Scale, VAS) referred to the emergency department of Imam Khomeini Hospital in Sari, Iran, were randomly assigned to two groups. The intervention group received 30 mg intravenous ketorolac and inhaled salbutamol (5 puffs), while the control group received ketorolac and a placebo inhalation. Pain intensity, vital signs, and symptoms such as nausea and vomiting were recorded at baseline and at intervals of 10, 20, 30, 45, 60, and 120 minutes after treatment.

Results: Pain intensity significantly decreased over time in both groups ($p < 0.001$), but the reduction was significantly greater in the salbutamol group at all measured intervals ($p < 0.001$). The intervention group also showed significant differences in heart rate and systolic blood pressure compared to controls. Oxygen saturation (SpO_2) was consistently higher in the control group, though changes over time were similar between groups. No serious side effects were reported.

Conclusion: Inhaled salbutamol appears to be a safe and effective adjunct for reducing pain in patients with acute renal colic and may improve certain physiological parameters. Its ease of use and non-opioid profile make it a promising option in emergency care settings.

Cite this article as: Hosseini SM, Goli Khair I, Khodadadi H. Effect of Inhaled Salbutamol on Pain Severity in Patients Presenting with Acute Renal Colic: A Double-Blind Randomized Clinical Trial. *Transl Health Rep.* 2025;1(1):21. <https://doi.org/10.22034/thr.2025.531758.1016>

Introduction

Renal colic is one of the most intense and debilitating forms of acute pain encountered in emergency medicine. It typically arises due to the sudden obstruction of urinary flow, most commonly caused by urolithiasis (urinary tract stones) (1, 2). The pain, which is often described as sharp and cramping, can radiate from the flank to the groin and is frequently accompanied by nausea, vomiting, hematuria, and restlessness (3). Patients experiencing renal colic often describe it as one of the most excruciating pains they have ever endured—

comparable in intensity to childbirth. Given its severity, the immediate and effective management of pain is the cornerstone of treatment in emergency departments (EDs) worldwide (4).

Currently, the mainstay pharmacologic treatments for renal colic include nonsteroidal anti-inflammatory drugs (NSAIDs) and opioids. NSAIDs, such as ketorolac, are preferred due to their ability to inhibit prostaglandin synthesis, reduce ureteral smooth muscle tone, and alleviate inflammation (5, 6). Despite their effectiveness, NSAIDs require intravenous or intramuscular administration, which can be time-consuming in a busy

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emergency setting. Moreover, opioids, while potent analgesics, are associated with a range of adverse effects such as respiratory depression, sedation, nausea, and potential for misuse or dependence (7). These limitations underscore the need for alternative or adjunctive treatments that are both effective and safe.

Salbutamol, also known as albuterol, is a β_2 -adrenergic agonist primarily used in the treatment of asthma and other obstructive pulmonary diseases due to its bronchodilator effects (8). Its mechanism of action involves the relaxation of smooth muscle through β_2 receptor stimulation. Interestingly, this property has raised the possibility of its application beyond respiratory conditions (9). Experimental and limited clinical data suggest that salbutamol may also relax smooth muscles in the urinary tract, potentially facilitating stone passage and reducing colic pain. The rapid onset of action via inhalation (typically within 1–2 minutes) and favorable safety profile make salbutamol an attractive candidate for use in acute pain scenarios like renal colic (10).

Despite these theoretical advantages, clinical evidence regarding the use of inhaled salbutamol for renal colic remains scarce. Most studies on adjunct therapies for renal colic focus on other drug combinations or alternative delivery routes, and only a few have explored the potential role of β_2 -agonists in this context. In addition, the limited research available has shown mixed results, and no consensus has yet been reached on whether salbutamol can meaningfully contribute to pain relief in renal colic patients.

This study aims to address this gap in knowledge by evaluating the effectiveness of inhaled salbutamol in reducing pain intensity among patients presenting with acute renal colic to the emergency department. By comparing a group receiving standard treatment with intravenous ketorolac and salbutamol inhalation to a control group receiving ketorolac and placebo, this randomized double-blind clinical trial seeks to provide evidence on the potential role of inhaled salbutamol as a safe, accessible, and non-opioid adjunct for pain management in renal colic.

Materials and Methods

Study Design and Setting

This study was designed as a double-blind, randomized, controlled clinical trial conducted in the emergency department of Imam Khomeini Educational Hospital in Sari, Iran. The research was approved by the institutional ethics committee, and all participants provided written informed consent before enrollment.

Participants

A total of 204 patients aged 18 years and older, presenting with moderate to severe acute renal colic

(based on the Visual Analog Scale [VAS]) and confirmed or suspected urinary tract stones, were included. Patients were selected through convenience sampling. Inclusion criteria consisted of: (1) clinical diagnosis of renal colic, (2) pain score ≥ 6 on the VAS, and (3) ability to provide informed consent. Exclusion criteria included: (1) known hypersensitivity to salbutamol or ketorolac, (2) history of chronic pulmonary disease requiring regular β_2 -agonist use, (3) hemodynamic instability, (4) recent use of opioid analgesics prior to arrival, and (5) pregnancy or lactation.

Randomization and Blinding

Participants were randomly assigned to two equal groups (intervention and control) using a computer-generated random number table. Allocation was concealed using sequentially numbered, opaque, sealed envelopes. Both patients and healthcare providers administering treatments were blinded to group assignments. The inhalers used for salbutamol and placebo were identical in appearance.

Interventions

- **Intervention group:** Received 30 mg of intravenous ketorolac along with five puffs (100 mcg per puff) of inhaled salbutamol administered via a metered-dose inhaler (MDI) with a spacer. The dose was repeated every 20 minutes up to three times within the first hour, based on the patient's response.
- **Control group:** Received 30 mg of intravenous ketorolac and a matched placebo inhalation following the same administration protocol as the intervention group.

Outcome Measures

The primary outcome was pain intensity, measured using the Visual Analog Scale (VAS) at baseline (prior to intervention) and at 10, 20, 30, 45, 60, and 120 minutes post-intervention.

Secondary outcomes included changes in vital signs—heart rate, respiratory rate, blood pressure (systolic and diastolic), and oxygen saturation (SpO_2)—as well as the presence of nausea or vomiting.

Data Collection

Baseline demographic and clinical data were collected, including age, gender, history of kidney stones, side of pain, prior medication use, and ultrasound findings. Pain scores and vital signs were recorded at specified intervals. Any adverse effects observed or reported during the study period were documented.

Statistical Analysis

Data were analyzed using SPSS software. Descriptive statistics were used to summarize baseline characteristics. Independent t-tests and Mann–Whitney U tests were applied for between-group comparisons, while repeated measures ANOVA and the Friedman test were used to assess within-group changes over time. A Generalized Estimating Equation (GEE) model evaluated the interaction effect of time and intervention. A p-value of <0.05 was considered statistically significant.

Results

A total of 204 patients diagnosed with acute renal colic were enrolled and completed the study. Participants were randomized into two groups: 104 patients received standard treatment with 30 mg intravenous ketorolac and placebo inhalation (control group), while 100 patients received the same dose of ketorolac combined with five puffs of inhaled salbutamol (intervention group). Baseline demographic characteristics were similar between the two groups, with no statistically significant differences observed ($p > 0.05$), confirming adequate randomization.

Pain Intensity

Pain intensity, assessed using the Visual Analog Scale (VAS), was the primary outcome of the study. At baseline, the intervention group reported a significantly higher pain score than the control group (7.86 ± 0.38 vs. 7.60 ± 0.57 , $p < 0.001$). However, following treatment, pain scores declined significantly in both groups. Notably, the intervention group exhibited a more rapid and sustained reduction in pain at all subsequent time points (10, 20, 30, 45, 60, and 120 minutes) compared to the control group ($p < 0.001$ at each time point).

As shown in Table 1, by 120 minutes post-treatment, the average pain score in the intervention group decreased to 2.01 ± 0.10 , while in the control group it remained higher at 3.04 ± 0.80 . These findings suggest that the addition of inhaled salbutamol significantly accelerated and enhanced pain relief.

Physiological Parameters

Oxygen Saturation (SpO_2)

Although baseline SpO_2 was slightly higher in the control group, both groups showed a significant increase in SpO_2 over time ($p < 0.001$ within groups). Between-group comparisons revealed statistically significant differences at every time point, favoring the control group ($p < 0.01$). However, the intervention group showed consistent improvement from baseline (96.89% to 99.33%), indicating that salbutamol may contribute positively to oxygenation status. The GEE model (Table 2) confirmed a significant effect of time ($p < 0.001$) and group ($p = 0.050$), although the group-by-

time interaction was not significant ($p = 0.095$), suggesting parallel trends in both groups.

Heart Rate

At baseline, heart rate was higher in the intervention group (82.28 ± 7.41 bpm) than in the control group (85.65 ± 8.56 bpm, $p = 0.002$). Both groups experienced a steady decline in heart rate over time ($p < 0.001$). However, the reduction was significantly slower in the intervention group, as confirmed by the significant group \times time interaction in the GEE model ($p = 0.001$). This may reflect the mild sympathomimetic effect of salbutamol.

Systolic Blood Pressure (SBP)

SBP values were consistently higher in the intervention group at all measured time points ($p < 0.01$). While SBP gradually declined in both groups over the study period ($p < 0.001$), the group-by-time interaction was not statistically significant ($p = 0.230$), indicating that the rate of change was similar. The higher SBP in the intervention group may reflect transient β_2 -mediated vascular effects.

Diastolic Blood Pressure (DBP)

There were no significant between-group differences in DBP at any measurement point ($p > 0.05$). Within-group comparisons showed a slight but statistically significant increase over time in both groups ($p < 0.001$ for control; $p = 0.004$ for intervention), though these changes were clinically modest and the group \times time interaction was not significant.

Respiratory Rate

Respiratory rates remained relatively stable throughout the observation period, with both groups exhibiting a slight decline over time ($p < 0.001$). No significant differences between groups were observed until the 120-minute mark, at which point the intervention group had a slightly higher respiratory rate (18.01 ± 0.41 vs. 17.83 ± 0.81 ; $p = 0.042$). The GEE analysis did not identify a significant group or interaction effect for this parameter.

Interaction Analysis (GEE Model)

To further examine the effect of time and treatment group on measured outcomes, a Generalized Estimating Equation (GEE) model was applied (see Table 2):

- **SpO_2 :** Significant effects of group ($p = 0.050$) and time ($p < 0.001$) were observed, but no significant interaction ($p = 0.095$), indicating similar improvement trajectories in both groups.
- **Heart Rate:** Significant effects of group ($p = 0.002$), time ($p < 0.001$), and their interaction ($p = 0.001$),

showing that the rate of decline differed between groups.

- **Systolic BP:** Significant effects of group ($p = 0.014$) and time ($p < 0.001$) were found, with no interaction ($p = 0.230$).
- **Diastolic BP and Respiratory Rate:** No significant effects were observed for group, time, or interaction.

- **Pain Intensity:** Strong effects were observed for group ($p < 0.001$), time ($p < 0.001$), and group \times time interaction ($p < 0.001$), confirming that the intervention significantly accelerated pain reduction compared to control.

Table 1: Comparison of Vital Signs and Pain Scores Over Time Between Groups

Variable	Group	Pre-Intervention	10 min	20 min	30 min	45 min	60 min	120 min	p-value (time trend)
SpO ₂ (%)	Control	97.66 ± 1.63	97.69 ± 2.32	97.91 ± 2.43	98.53 ± 1.34	98.87 ± 1.24	99.14 ± 2.20	99.61 ± 1.07	< 0.001 (b)
	Intervention	96.89 ± 2.91	97.16 ± 2.08	97.68 ± 1.75	98.05 ± 1.64	98.52 ± 1.31	99.00 ± 1.07	99.33 ± 0.81	< 0.001 (b)
	p-value	0.002 (a)	0.001 (a)	0.008 (a)	0.002 (a)	0.008 (a)	0.007 (a)	< 0.001 (a)	
Heart Rate (bpm)	Control	85.65 ± 8.56	84.59 ± 7.61	83.06 ± 6.64	81.65 ± 5.96	80.52 ± 4.72	79.15 ± 3.82	78.02 ± 2.95	< 0.001 (b)
	Intervention	82.28 ± 7.41	81.45 ± 6.48	80.46 ± 5.68	79.58 ± 5.14	78.81 ± 4.54	77.93 ± 4.11	77.27 ± 3.60	< 0.001 (b)
	p-value	0.002 (a)	0.001 (a)	0.003 (a)	0.004 (a)	0.008 (a)	0.011 (a)	0.039 (a)	
Systolic BP (mmHg)	Control	118.52 ± 11.56	119.08 ± 10.35	119.00 ± 10.04	118.77 ± 9.61	118.98 ± 8.64	118.38 ± 8.45	118.01 ± 7.66	0.001 (b)
	Intervention	122.03 ± 9.44	122.40 ± 8.63	122.34 ± 7.83	121.92 ± 7.53	121.57 ± 6.99	121.12 ± 6.49	120.75 ± 6.29	< 0.001 (b)
	p-value	0.003 (a)	0.001 (a)	0.001 (a)	0.002 (a)	0.005 (a)	0.003 (a)	0.003 (a)	
Diastolic BP (mmHg)	Control	74.93 ± 6.95	75.70 ± 6.46	75.87 ± 5.96	76.09 ± 5.67	76.08 ± 5.58	75.93 ± 5.51	76.01 ± 5.21	< 0.001 (b)
	Intervention	74.88 ± 8.22	75.88 ± 7.09	75.74 ± 6.60	75.75 ± 6.16	75.68 ± 6.12	75.81 ± 6.07	75.94 ± 5.94	0.004 (b)
	p-value	0.765 (a)	0.828 (a)	0.963 (a)	0.830 (a)	0.811 (a)	0.822 (a)	0.654 (a)	
Respiratory Rate (breaths/min)	Control	18.23 ± 1.13	18.13 ± 1.10	17.96 ± 0.79	17.93 ± 0.71	17.88 ± 0.69	17.82 ± 0.80	17.83 ± 0.81	< 0.001 (b)
	Intervention	18.27 ± 1.11	18.18 ± 1.15	18.01 ± 0.90	17.95 ± 0.78	17.93 ± 0.69	17.99 ± 0.64	18.01 ± 0.41	< 0.001 (b)
	p-value	0.478 (a)	0.467 (a)	0.750 (a)	0.985 (a)	0.691 (a)	0.062 (a)	0.042 (a)	
Pain Score (VAS)	Control	7.60 ± 0.57	7.12 ± 0.90	6.39 ± 0.86	5.71 ± 0.89	4.93 ± 0.90	4.02 ± 0.86	3.04 ± 0.80	< 0.001 (b)
	Intervention	7.86 ± 0.38	6.00 ± 0.55	4.32 ± 0.67	3.14 ± 0.60	2.47 ± 0.56	2.02 ± 0.20	2.01 ± 0.10	< 0.001 (b)
	p-value	< 0.001 (a)	< 0.001 (a)	< 0.001 (a)	< 0.001 (a)	< 0.001 (a)	< 0.001 (a)	< 0.001 (a)	

Note: a = Mann-Whitney U test (between groups); b = Friedman test (within group over time)

Discussion

The findings of this study suggest that salbutamol, a β_2 -adrenergic agonist typically used in airway management, can significantly enhance pain relief and favorably influence certain physiological parameters—namely SpO₂, heart rate, and systolic blood pressure—when used alongside standard analgesia.

The primary outcome—pain intensity—was significantly lower in the intervention group at all post-treatment intervals, with a faster and more pronounced reduction compared to the control group. While ketorolac alone provided measurable analgesia in both groups, the combination with inhaled salbutamol yielded superior outcomes. This supports the hypothesis that β_2 -agonists, through their smooth muscle-relaxing properties, may reduce ureteral spasm, facilitate the passage of ureteral stones, and subsequently amplify pain relief. This mechanism aligns with the known pharmacodynamics of salbutamol and corroborates its theoretical role in managing colicky pain (10, 11).

The improvement in SpO₂ and heart rate observed in the intervention group, although not uniformly superior to the control group at every time point, further

indicates the systemic influence of salbutamol beyond its bronchodilatory action. These findings are biologically plausible, as β_2 -agonists can enhance peripheral perfusion and oxygen delivery by reducing smooth muscle tone in vasculature and improving respiratory efficiency (12). Interestingly, the decline in heart rate was slower in the intervention group, which may be attributed to the mild sympathomimetic effects of salbutamol, requiring further investigation to clarify whether this response reflects autonomic modulation or a transient side effect.

Our results are consistent with prior studies investigating multimodal approaches to renal colic. Eidinejad et al. reported comparable analgesic efficacy among three doses of IV ketorolac (10, 20, and 30 mg), highlighting the drug's ceiling effect (13). Mahmoudi-Andehkordi et al. demonstrated that ketorolac combined with dexamethasone led to reduced pain and emergency department revisits post-stent removal (14). Similarly, Razi et al. found that the addition of dexamethasone to ketorolac decreased opioid need and nausea, emphasizing the benefit of combining anti-inflammatory agents for enhanced symptom control (15).

In contrast, Johnson et al. evaluated intravenous salbutamol in patients with renal colic and found no significant advantage over placebo, with a mild increase in adverse effects (10). The divergence from our findings may stem from differences in administration route

(inhaled vs. intravenous), pharmacokinetics, and dosing schedules. Our study, notably, did not report any serious adverse events, underscoring the relative safety of inhaled salbutamol in this setting.

Table 2: Effect of Group, Time, and Interaction on Outcome Variables (GEE Model)

Variable	Factor	OR (95% CI)	p-value
SpO₂	Group (Intervention)	1.005 (1.000, 1.011)	0.050
	Group (Control)	1 (Reference)	—
	Time	1.002 (1.002, 1.002)	<0.001
	Group × Time Interaction	1.000 (0.999, 1.000)	0.095
Heart Rate	Group (Intervention)	1.037 (1.013, 1.062)	0.002
	Group (Control)	1 (Reference)	—
	Time	0.995 (0.994, 0.996)	<0.001
	Group × Time Interaction	0.997 (0.996, 0.999)	0.001
Systolic BP	Group (Intervention)	0.973 (0.952, 0.994)	0.014
	Group (Control)	1 (Reference)	—
	Time	0.999 (0.998, 0.999)	<0.001
	Group × Time Interaction	1.001 (1.000, 1.001)	0.230
Diastolic BP	Group (Intervention)	1.001 (0.977, 1.026)	0.912
	Group (Control)	1 (Reference)	—
	Time	1.001 (1.000, 1.002)	0.229
	Group × Time Interaction	1.000 (0.999, 1.001)	0.895
Respiratory Rate	Group (Intervention)	0.999 (0.984, 1.013)	0.852
	Group (Control)	1 (Reference)	—
	Time	0.999 (0.998, 1.000)	0.071
	Group × Time Interaction	0.999 (0.998, 1.001)	0.290
Pain Intensity	Group (Intervention)	1.296 (1.262, 1.331)	<0.001
	Group (Control)	1 (Reference)	—
	Time	0.897 (0.895, 0.898)	<0.001
	Group × Time Interaction	1.030 (1.026, 1.035)	<0.001

OR: Odds Ratio; **CI:** Confidence Interval

Note: A significant interaction indicates that the effect of time differs between intervention and control groups.

The broader potential of β_2 -agonists in visceral pain management has been noted in other contexts. Frugier et al. observed significantly faster relief of abdominal pain following peanut-induced allergic reactions with inhaled salbutamol versus placebo (16). Similarly, studies on irritable bowel syndrome and dysmenorrhea have hypothesized that β_2 -agonists may mitigate visceral pain through smooth muscle relaxation or modulation of sensory pathways. These findings align with our hypothesis and suggest a novel role for salbutamol in select acute pain settings.

Additionally, the current findings are in line with the work of Al-Khalasi et al., who compared nasal and intravenous ketorolac and found no significant differences in analgesic efficacy (17). Their work supports the broader argument that route of administration can be tailored based on patient preference and clinical context, without compromising effectiveness—similar to our use of a non-invasive

inhalation route to achieve effective adjunctive analgesia.

Despite its promising results, this study has limitations that must be acknowledged. First, although adequately powered for primary outcomes, the sample size may still restrict the detection of rarer side effects and limits subgroup analysis. Second, the short duration of follow-up (limited to 120 minutes) precludes understanding of longer-term outcomes, including stone passage rates and pain recurrence. Third, potential confounders such as stone size, location, prior analgesic use, and hydration status were not fully stratified despite randomization. Fourth, pain intensity was assessed using the Visual Analog Scale (VAS), a subjective measure influenced by individual perception and psychological factors. Finally, this was a single-center study, which may impact the generalizability of findings to other settings or populations.

Future research should involve multicenter, larger-scale trials with extended follow-up to assess sustained efficacy, recurrence, and safety. Additionally, studies

that examine stone passage rates and objective endpoints, such as time to analgesic rescue or need for further urologic intervention, will help clarify the broader clinical utility of inhaled salbutamol in renal colic management. Exploring its role in other visceral or spastic pain syndromes may also uncover new therapeutic applications.

Conclusion

This study demonstrated that inhaled salbutamol, when used as an adjunct to intravenous ketorolac,

significantly enhances pain relief and improves selected physiological parameters in patients with acute renal colic. Given its favorable safety profile, rapid onset of action, and ease of administration, inhaled salbutamol may be considered a valuable non-opioid adjunct in emergency pain management. Further research with larger, multicenter trials is recommended to validate these findings and explore its broader clinical application.

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