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Role of Selective Cyclooxygenase-2 Inhibitors in Renal Colic Pain Reduction and Improvement: A Systematic Review of Clinical Trials

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Abstract

Renal colic is an irritating condition that develops after obstruction of the ureter. Selective cyclooxygenase-2 inhibitors are types of non-steroidal anti-inflammatory drugs (NSAIDs) that have beneficial role in treatment various diseases. Hence, this systematic review summarizes the current knowledge about the role of selective cyclooxygenase-2 (COX-2) inhibitors as painkiller in renal colic pain management. The present systematic review was conducted according to the guidelines of the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) statements. Until September 2022, PubMed/Medline, Scopus, Web of Science, and Google Scholar databases were searched using the relevant keywords including "Selective Cyclooxygenase-2 Inhibitors", "Parecoxib", "Celecoxib", "Rofecoxib", "Renal Colic Pain" and "Ureteral Colic Pain". Of 64 identified records through database searching, 6 randomized controlled trials (RCTs) were selected for this systematic review. The sample size in RCTs were between 53 and 338. The range of subject's age was from 18 to 69. Overall, the evidence of this review revealed that the selective COX-2 inhibitors particularly celecoxib and parecoxib could alleviate renal colic pain in most of the studies through decreasing relevant pain score. Overall, selective COX-2 inhibitors seem to be effective in alleviating renal colic pain. However, further high quality assessments are required for demonstrating therapeutic role of selective COX-2 inhibitors against renal colic pain.

Introduction

Renal colic refers to painful and emergency conditions that occurs due to obstruction of the ureter [1,2]. Therefore, the term ureteral colic can describe this condition more accurately than renal colic. Renal colic manifests itself with high intensity and continuous pain. The renal colic pain originates from obstruction and distension of different parts of urinary system affected by stone including ureter, pelvicalyceal system, and renal capsule [1]. Renal colic is a prevalent condition in emergency departments that could involve people with an estimation as 1-15% during a lifetime. The prevalence of renal colic varies under the influence of various factors including age, sex, nationality, and geographical location [3]. Previous reports have estimated that renal colic appears in 240 per 100,000 persons [4,5]. Furthermore, statistics have indicated that the renal colic has higher incidence in men than women with a ratio of 3-2 to 1 [6]. Urinary calculi or urolithiasis or nephrolithiasis is recognized as the most important causative agent for development of renal colic pain [7]; however, several conditions such as lymphadenopathy, formation of blood clots caused by upper tract bleeding and sloughed renal papilla are other causes responsible for development of renal colic pain [1]. It has been documented that renal colic develops due to renal stones in 56% of cases [8]. It has been reported that approximately 600,000 patients with acute pain caused by renal calculi are annually admitted to the emergency departments in the United States which imposes a cost more than 2 billion dollars on the healthcare system [9]. Patients suffering from renal colic usually refer to the emergency departments with clinical manifestations such as severe loin pain, radiated pain to the flank, groin, and testes, nausea and vomiting [1,10]. Patients suffering from renal colic mention the pain caused by this disease as the worst pain they have ever experienced [11,12]. Renal failure, loss of kidney function and septicemia are serious and life threatening consequences of not treating renal colic on time. Hence, it is an emergency situation that requires quick management in the emergency departments [13]. Immediate admission to the hospital is considered as the main solution in the management of renal colic pain [14]. After diagnosis of renal colic with ultrasonography, radiography and computed tomography, therapeutic procedures such as surgery and medication can be effective in reducing pain [8,15]. Among these procedures, administration of analgesics including non-steroidal anti-inflammatory drugs (NSAIDs) or opioids is a regular procedure for pain relief; however, recently the administration of drugs such as alpha-blockers is recommended [11,16]. Cyclooxygenase-2 (COX-2) inhibitors are a class of NSAIDs which exert their therapeutic effects against various types of diseases including inflammatory diseases and cancer. They act through the inhibition of COX-2 as producer of prostanoids [17]. Hence, the present study reviews systematically the current knowledge about the role of selective COX-2 inhibitors as pain reliever drugs for renal colic pain management.

Methods

Literature search and selection criteria

The present systematic review was carried out according to the guidelines of the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) statements.

Search Strategy

A systematic search was made on electronic databases, including Scopus, PubMed/Medline, Web of Science, and Google Scholar via keywords selected from Medical Subject Headings (MeSH). Selection of keywords was performed based on the PICO style (Participants, Intervention, Comparison, and Outcome). The following keywords: "Selective Cyclooxygenase-2 Inhibitors", "Parecoxib", "Celecoxib", "Rofecoxib", "Renal Colic Pain" and "Ureteral Colic Pain" were used for searching from databases. The search was done based on English language. The process of search was done by two authors, independently. In the current systematic review, the documents including dissertations, expert opinion and conference presentations was ignored due to imprecise results.

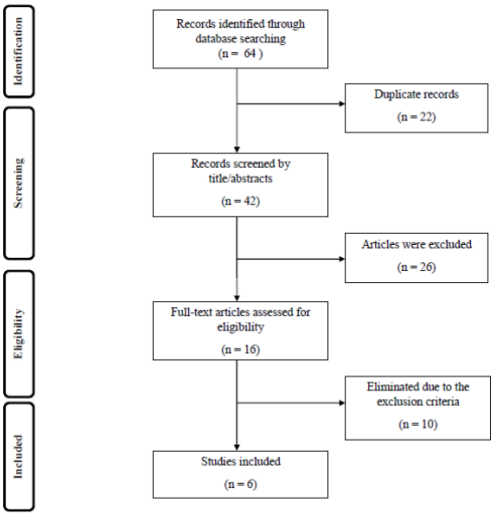

Figure 1: Flow chart of study selection

Eligibility Criteria

All relevant studies published until September 2022 were eligible in the current study. The present systematic review included all articles that evaluated the role of selective COX-2 inhibitors in renal colic pain management.

cyclooxygenase-2 inhibitors	Route of Administration	Drug Dosing	Study Design	Size Included (No. of Males)	Groups (Size)	Pain Measurement	Key Findings	Author (Year) (Country) (Ref)
Parecoxib	Intravenous	40 mg	A randomized, double blinded, controlled trial	203 patients with acute renal colic because of ureterolithiasis	- Group 1: received 40 mg intravenous Paracetamol infusion - Group 2: received 40 mg intravenous Parecoxib infusion	-Pain analogue score evaluation before and after treatment (30 min) -Rescue analgesia	- Paracetamol treatment decrease the average of pain analogue score from 7.6 to 3.8 in patients (P <.001). The mean pain analogue score decrease from 7.8 to 3.4 in parecoxib treated patients (P <.001). - Rescue analgesia were required in 35.3% of paracetamol treated patients and 26.7% of parecoxib treated patients (P = 0.187). Moreover, 2% of paracetamol treated patients and 3% of parecoxib treated patients experienced minor adverse events (P=0.683). Overall, these results revealed that Paracetamol and Parecoxib were effective in reduction of pain and treatment for patient with acute renal colic.	Al-Terki et al (2021) (Kuwait) [24]
Parecoxib	Intravenous	40 mg	A prospective double-blind and randomized trial	233 adult patients (18–65 years) who presented with acute ureteric colic (Group 1: 81 male patients Group 2: 80 male patients)	- Group 1: received intravenous parecoxib 40 mg plus placebo (119 patients) - Group 2: received intravenous Parecoxib 40 mg plus phloroglucinol 80 mg (114 patients)	-Visual analog scale (VAS) - Pain intensity difference (PID) - Pain relief - Rescue analgesics	- The mean baseline VAS scores were 81.7 ± 13.6 in treatment group with parecoxib and 83.4 ± 10.5 in parecoxib plus phloroglucinol treated patients, respectively. - The results showed that mean PID at 15 and 30 min in patients treated with parecoxib was 24.7 ± 18.2 and 38.9 ± 23.8 mm, respectively. Additionally, the average of PID at 15 and 30 min after administration of parecoxib plus phloroglucinol was 31.3 ± 19.6 and 47.2 ± 24.1 mm, respectively. Furthermore, the differences in PID level at 15 and 30 min were statistically meaningful between parecoxib and parecoxib plus phloroglucinol groups (P_{15min} = 0.011, P_{30min} = 0 .013). Moreover, there was no meaningful alterations in the average of PID between the parecoxib and parecoxib plus phloroglucinol treatments at any mentioned time. - Pain relief at 2 hours was found in 84.0 % of parecoxib administrated groups and 86.8 % of parecoxib plus phloroglucinol administrated groups, but no statistical significant change was observed (P = 0.542). - Rescue analgesics at2 hours was needed by 14.3% of parecoxib treated patients and 6.1% of parecoxib combined with phloroglucinol treated patients, which exhibited a statistical meaningful change between these groups (P = 0.041). Furthermore, 7.6 % of patients in the monotherapy regimen and 8.8 % in the parecoxib combined with phloroglucinol treatment had adverse events. In general, treatment of patients with Parecoxib in combination with phloroglucinol could alleviate renal colic pain.	Fu et al (2014) (China) [19]
Celecoxib	Oral (Capsules)	400 mg immediately and 200 mg every 12 h	A randomized, prospective study	103 patients with ureteral colic due to distal ureteral stones (Group 1: 20 men Group 2: 21 men Group 3: 18 male patients)	- Group 1: received capsules of naftopidil 50 mg/day (35 patients) - Group 2: received capsules of naftopidil 50 mg/day plus celecoxib 200 mg (35 patients) - Group 3: received capsules of celecoxib 200 mg (33 patients)	- VAS	- The results showed that the average pain episodes number was obtained as 2.22 ± 0.94, 1.37 ± 1.33 and 1.42 ± 1.17 in patients treated with naftopidil, naftopidil plus celecoxib and celecoxib, respectively (P = 0.003). In addition, there was a remarkable change between naftopidil and naftopidil plus celecoxib treated groups, and groups 1 and 3 for the VAS score on days 3 and 7, respectively (P = 0.000 and P = 0.000, respectively). Furthermore, serious side effects was not observed in treated patients. Overall, treatment with naftopidil and celecoxib could effectively drop the pain frequency and intensity caused by renal colic.	Lin Lv and Tang (2014) (China) [20]
Parecoxib	Intravenous	40 mg	A phase i.v., multicenter, randomized, double-blind, double-dummy, comparative, active-controlled study	338 adult patients (18–65 years) with acute renal colic (Group 1: 110 men Group 2: 103 men)	Group 1: received intravenous parecoxib 40 mg plus placebo (174 patients) Group 2: received intravenous ketoprofen 100 mg plus placebo (164 patients)	- VAS - PID	- The average variation from baseline in VAS 30 min after treatment was approximately 43 mm. Moreover, no considerable change was seen between the parecoxib and ketoprofen treated groups for VAS scores at different times. - The mean (SD) mPID30 min was obtained as 33.84 (24.61) and 35.16 (26.01) for group 1 and group 2, respectively. The 95% CI was obtained as 6.53 for treatment difference (parecoxib-ketoprofen). Additionally, 61% of subjects located in parecoxib group and 55% of patients assigned to ketoprofen group stated complete pain relief 30 min after treatment. Furthermore, 25.9% of subjects treated with parecoxib and 28% of patients treated with ketoprofen showed mild or moderate adverse effects. In general, parecoxib ameliorated renal colic pain due to its well toleration and safety.	Glina et al (2011) (Brazil) [23]
Celecoxib	Oral (Capsules)	400 mg after admission to emergency department and 200 mg every 12 hours for 10 days	A prospective randomized double-blind study	53 adult patients (20-67 years) with acute renal colic due to ureteral stones (Group 1: 22 male subjects Group 2: 15 male subjects)	Group 1: received capsules of celecoxib 200 mg (29 patients) Group 2: received oral placebo (24 patients)	- Pain analog scores	- The results showed no noticeable change in mean pain score between the celecoxib (8.24 ±1.75) and placebo groups (8.33 ±1.80, P =0.85). No meaningful variation was observed in pain analog scores after treatment (celecoxib 2.6 ±2.7 vs placebo 3.5 ±3.4, P = 0.71) for the celecoxib and placebo groups. Average pain stated by subjects in the celecoxib group for days 1 to 5 was 3.6 ±2.7 in comparison with 3.5 ±2.9 in the placebo subjects (P = 0.80). Average pain scores for days 6 through 10 were 2.3 ±2.2 and 2.4 ±2.8 for celecoxib and placebo respectively (P = 0.79). Furthermore, no positive outcome of celecoxib was seen on narcotic administration. Overall, authors concluded that celecoxib did not alleviate stone passage or reduce narcotic use for acute renal colic.	Phillips et al (2009) (USA) [21]
Rofecoxib	Oral (Capsules)	a single dose of 50 mg	A double-blind, placebo controlled trial	110 adult subjects (18-69 years) with ureterolithiasis (Group 1: 29 male subjects Group 2: 28 male subjects Group 3: 27 male subjects)	Group 1: received capsules of rofecoxib 50 mg (36 patients) Group 2: received capsules of diclofenac 50 mg (39 patients) Group 3 or control group: received placebo capsules contained mannitol (35 patients)	- VAS	- Findings demonstrated that mean VAS scores in the rofecoxib, diclofenac and placebo treated subjects did not differ significantly (p = 0.22). It was not observed a noticeable change in VAS scores at any time (p = 0.24). Furthermore, any significant changes was observed in treatment withdrawals associated with pain (p = 0.64) and withdrawals in general (p = 0.67). In addition, patients did not indicate any clinically relevant unexpected results during therapy. In general, this experiment demonstrated that administration of rofecoxib had no relevant morphine sparing effect.	Engeler et al (2005) (Switzerland) [22]

Table 1: Summary of available literature on the therapeutic effect of selective cyclooxygenase-2 inhibitors in management of renal colic pain.

Studies	Jaded Scale Item			Total	Quality
	Randomization	*Blinding*	*An account of all patients*		
Al-Terki et al (2021)	2	1	1	4	High
Fu et al (2014)	2	2	1	5	High
Lin Lv and Tang (2014)	1	0	1	2	Low
Glina et al (2011)	2	2	1	5	High
Phillips et al (2009)	2	1	1	4	High
Engeler et al (2005)	2	2	1	5	High

Table 2: Jaded scale scoring for reporting quality of RCTs included in this study.

Articles with insufficient information including case reports, observational studies, letters to the editor, reviews, conferences, and qualitative papers were not selected for this study.

Data Extraction

The literature was screened for extraction of required data by two investigators independently. The required data were used including name of drug (selective COX-2 inhibitors), administration route of drug, the dosage of the selective COX-2 inhibitors, study design, sample size, number of male patients, range of patient's age, groups, pain measurement, the mean and SD of pain score before and after treatment with the selective COX-2 inhibitors, first author's last name, country of origin and year of publication.

Quality Assessment

In order to evaluate the randomized controlled trials (RCTs) for their methodological quality, the Jadad scale was used. Based on Jadad scale, the score of each study varies from 0 to 5. The Jadad scale evaluate various items including randomization (Maximum points=2), blinding (Maximum points=2) and an account of all patients (Maximum points=1). The RCTs with maximum scores ⩽2 was considered as low quality. On the other hand, the RCTs with minimum scores ⩾3 was considered as high quality [18].

Study Characteristics

The process of study selection has been indicated in detail in Figure-1. After searching through mentioned databases, 64 studies were initially identified. There were 42 studies remaining after the removal of duplicates. Of these, 26 studies that did not have the inclusion criteria of the study were removed. Then, 16 scientific documents were chosen based on the research topic. Finally, 6 articles were included in the current systematic review after critical analysis. There were 6 RCTs included in final analyses. The sample size in RCTs was considered between 53 and 338. The range of subject's age was from 18 to 69, representing that all patients were adult. All included publications were done after 2000. The included studies were performed in China with two studies [19,20], USA with one study [21], Switzerland with one study [22], Brazil with one study [23] and Kuwait with one study [24]. Table-1 summarizes the characteristics of the articles included in the current systematic review.

Quality Assessment

According to the Jadad scale for reporting the quality of RCTs, five studies had high quality (Maximum points ⩽2) and only one study had low quality (Maximum points ⩾3) (Table-2).

Discussion

Several studies have evaluated the impact of the selective COX-2 inhibitors in renal colic pain management. However, the results of all of them are not reliable. In the present systematic review, we attempted to study the effectiveness of the selective COX-2 inhibitors as pain reliever drugs for reducing renal colic pain. The findings of this systematic review revealed that the selective COX-2 inhibitors drugs such as celecoxib, parecoxib and rofecoxib are useful medications in the alleviation of ureteric colic pain. Ureteric colic is recognized as one of regular urologic emergency conditions. The incidence (approximately 12%) and recurrence rate (50%) of this disease has become an important challenge in emergency departments. It has been reported that the subjects with ureteric colic experience an unbearable pain with high severity [11]. Hence, pain management is the first important step after admission of subjects suffering from ureteric colic to the emergency departments [25]. Some events such as ureteral obstruction, smooth muscle contraction of the ureter and subsequently inflammation have been shown to be associated to development of renal colic pain [26,27]. There are several pieces of evidence about the origin of renal colic pain. Ureteric colic pain develops because of obstruction of various parts of urinary system including ureter and pelvis. The obstruction of ureter because of renal calculi could induce pressure on the wall of urinary tract. Ureteral spasm has been proposed as another event which makes the renal colic pain worse [11,28]. On the other hand, several lines of evidence have demonstrated that pressure on the pelvis can induce the provoking, production and release of mediators of acute inflammation including prostaglandins [11,26]. Furthermore, it has been indicated that obstruction of the ureter due to kidney stones could induce inflammation in ureter because of the production and release of prostaglandins [11,27]. There is also an experiment by Nakada and colleagues that have reported up-regulation of COX-2 mRNA and protein levels as producer of prostaglandins during ureteral obstruction [29].

Excessive production of prostaglandins in response to injury caused by obstruction of the ureter due to nephrolithiasis is associated with renal colic pain with high severity [11]. To date, administration of NSAIDs, opioid and antispasmodics medications are used as a therapeutic solution to relieve severe pain induced by ureteric colic in emergency departments [25,26]. The findings of several trials have revealed that the efficiency and safety of NSAIDs in ureteric colic pain management. It has been exhibited that NSAIDs could relieve renal colic pain better than opioids [26,30]. Nowadays, NSAIDs have become a popular choice in emergency departments for controlling renal colic pain [19]. The mechanism of action of NSAIDs is inhibition of prostaglandin E2 secretion as a potent inflammatory mediator [25]. The production of prostaglandin E2 is affected by the activity of COX-2 which is inhibited by NSAIDs [31]. The COX-2 activity could inhibit by nonselective and selective inhibitors [32]. There are several reports about the therapeutic role of NSAIDs with nonselective COX-2 inhibition properties including ibuprofen, ketorolac [33], and indomethacin on renal colic [34]. Recently, the tendency to use selective COX-2 inhibitors has increased due to their effectiveness in alleviating various types of acute pain and safety [19]. In this regard, previous studies have been recommended that celecoxib and parecoxib as two important selective COX-2 inhibitors NSAIDs could alleviate different pains caused by surgery [35,36] and also renal colic [20,24].

Ureteral contractility is an important event in development of renal colic pain which lead to prostanoid release [11]. Jerde et al. showed that celecoxib could reduce ureteral contractility and prostanoid release in vitro because of inhibition of COX-2 with high specificity [37]. Furthermore, the role of parecoxib as an available selective COX-2 inhibitors NSAIDs has been investigated on contractility of ureters of the pig in vivo. The authors concluded that parecoxib plays role in decreasing the contractility of non-obstructed ureter in pig [38]. Tissue damage [39-47], especially kidney damage caused by diabetes [8-50] causes renal colic pain. Antioxidants can prevent tissue damage by affecting enzyme activities [51-54]. There are low publications about the therapeutic impact of selective COX-2 inhibitors on renal colic pain management. Hence, more scientific documents is needed to evaluate more precisely the efficacy of selective COX-2 inhibitors on ureteric colic treatment. The major strength of the current experiment was that it reviewed the impact of selective COX-2 inhibitors in renal colic pain control systematically for the first time. Our systematic review had some limitations such as the quality of included study, various subject populations, different methods of pain evaluation and the route of medication's use as any other similar studies.

Conclusion

Taking together, selective COX-2 inhibitors particularly celecoxib and parecoxib could alleviate renal colic pain in most of the studies. The function of selective COX-2 inhibitors was better than conventional NSAIDs such as paracetamol and ketoprofen for management of renal colic pain through decreasing score of pain scale. Furthermore, toleration and safety of the selective COX-2 inhibitors were two important factors for choosing them in reducing ureteric colic pain. In conclusion, the present systematic review indicated that the selective COX-2 inhibitors can be administrate lonely or combined with more painkiller medications for ureteric colic pain management. Further RCTs are needed for demonstration of the effectiveness of selective COX-2 inhibitors in alleviating renal colic pain.

Competing Interest

The authors declare that there is no conflict of interest.

Author Contributions

Mehdi Mohammadian Amiri: monitoring of review, participation in data acquisition, interpretation of results, drafting of manuscript.

Mohammad Darvishi: Supervision of the review, writing and validation of the final version of the manuscript.

Shaimaa Hameed Fayyadh, Rosario Mireya Romero Parra, Ali Hussein Demin Al-Khafaji, Munther Abosaooda: Literature review, review analysis, validation of the final version of the manuscript.

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