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ORIGINAL ARTICLE

The Effects of Either Diclofenac Suppository, Intravenous Acetaminophen or their Combination on the Severity of Postoperative Pain in Patients Undergoing Spinal Analgesia during Cesarean Section.

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ABSTRACT

Background: Various medications such as opioids and non-steroidal anti-inflammatory drugs (NSAIDs) are used to alleviate discomfort following caesarean surgery. Particular attention has been paid to NSAIDs due to complications of opioids, and doctors use these medications as useful analgesics to manage various forms of pain. This research was conducted to evaluate the effect of either diclofenac suppository, intravenous acetaminophen or their combination on reduction of the severity of postoperative pain in patients undergoing caesarean section spinal analgesia.

Methods: This was comparative prospective interventional clinical study in Zagazig University Maternity Hospital during the period from August 2017 to December 2017. Includes 48 patients undergoing caesarean section. Patients were randomly divided (by alternation) into three groups of 16 patients, group A: 100 mg diclofenac suppository, group B: 1000 mg acetaminophen by intravenous infusion injection in 200 ml of 0.9 percent saline, group C: 100 mg diclofenac suppository and 500 mg intravenous acetaminophen. All patients underwent full clinical assessment and 24-hour pain follow-up. At the end of the surgery, pain severity was measured on a VAS scale at various intervals.

Results: The lowest mean pain severity was found in the combination group during the study and the highest was observed in the diclofenac group. There was significant difference of times of additional doses of analgesia which high in group diclofenac then group acetaminophen and the least times detected at combination group.

Conclusion: The combination of acetaminophen and diclofenac has stronger and longer analgesic effects than the single use of each drug.

Keywords; Diclofenac Suppository; Intravenous Acetaminophen; Postoperative; Spinal Analgesia; Cesarean Section.

INTRODUCTION

Cesarean section is one of the commonly performed surgeries, its rate is rising due to various reasons including advancing marital age, legal issues in the obstetric/gynecological department, the socio-economic status of the population and so on. According to the most recent figures, the overall global incidence of CS is 18.6 per cent, varying from 6.0 per cent in the least and more developed areas. Accordingly, the caesarean section is one of the community's health priorities [1] and postoperative complications management is of great importance [2].

Caesarean section (CS) typically causes mild to extreme pain for about 48 hours. Optimal perioperative pain control is needed, which not only helps the mother to ambulate early but also plays a key role in postoperative recovery after CS [3].

Postoperative pain is one of the most undesirable experiences of a patient undergoing surgery, such as caesarean section. It is necessary to take deliberate measures to prophylactically treat the pain. If postoperative pain develops, it should be handled early and vigorously, because extreme pain not only causes delayed discharge and low patient satisfaction, but can also induce a hyperalgesic disorder known as persistent postoperative pain (PPP). This stresses not just the patient, but the healthcare system as a whole as well. Latest studies have shown that the prevalence of PPP is as high as 40%. In addition, 18.3 percent of patients experience mild to extreme pain [4].

Surgeons should also be conscious of the severity of this issue and of all pharmacological agents used to avoid and treat postoperative pain. The mainstay of treatment to date has been the delivery of exogenous opioids such as morphine or fentanyl. However, pain is not always entirely relieved by such agents and patients also gain tolerance to such agents. Increased doses of opioids are evidently not without their adverse effects [5].

As a result of opioid complications, doctors have recently concentrated on non-steroidal anti-inflammatory drugs (NSAIDs) for pain control [6, 7]. Diclofenac is one of those medications, effective in postoperative pain relief and in reducing postoperative narcotics requirements [8, 9]. It can be successful mainly in the central nervous system by inhibiting cyclooxygenase and possibly by indirect effects on the serotonergic system. It quickly crosses the brain barrier and causes successful pain relief [8]. The objective of this study was to assess the effect of either diclofenac suppository, intravenous acetaminophen or their combination on the reduction of postoperative pain severity in patients undergoing caesarean section of spinal analgesia.

PATIENTS & METHODS

After obtaining approval of the ethics committee, comparative prospective interventional clinical study was carried out in Zagazig University Maternity Hospital during the period from August 2017 to December 2017. Includes 48 patients undergoing caesarean section. Patients were randomly divided into three groups, (16 patients) group A: 100 mg diclofenac suppository, (16 patients) group B: 1000 mg acetaminophen by intravenous infusion injection in 200ml of 0.9% saline, (16 patients) group C: 100 mg diclofenac suppository and 500 mg intravenous acetaminophen [10]. Written informed consent was obtained from all participants and the study was approved by the Research Ethics Committee of the Faculty of Medicine, University of Zagazig. Studies have been performed on research with human subjects in accordance with the Code of Ethics of the World Medical Association (Declaration Helsinki).

Inclusion criteria: Cesarean section for obstetric causes (breech, CPD...etc.), age between 18 and 40 years, term pregnancy, no history of diseases such as cardiovascular, hepatic and renal diseases, no history of drug dependency. **Exclusion criteria*:*** Having an allergic background to medications such as acetaminophen or local anesthetics, liver and kidney disease, diabetes, history of substance dependency, usage of analgesic drugs (opioid, NSAID, corticosteroid) during the last 8-12 hours.

All patients obtained demographic data after enrollment in the study age, weight and parity were estimated. Form of caesarean section, comprehensive medical history of each patient including medical and surgical history, history of neurological conditions and spinal surgery, history of general diseases, e.g. diabetes mellitus, history of drug dependency, laboratory investigations (complete blood count, liver enzymes, PT and PTT).

Preoperative hydration:

All participants were injected with 5 ml/kg of intravenous crystalloid fluid. All cesarean sections for patients of all groups were performed under spinal anesthesia using a 25 G needle using bupivacaine 0.5% without receiving any sedation. Spinal anesthesia has been done in a sitting position. Immediately after spinal injection, patients were placed in supine position with left uterine displacement.

Intra operative procedures:

During surgery, heart rate, oxygen saturation and blood pressure were monitored continuously for all patient. Intravenous antibiotic was given: ampicillin plus sulbactam (unasyn) 1.5 gm. were injected before fetal delivery. A normal surgical procedure was performed by means of a Pfannenstiel incision followed by a transverse lower uterine segment incision, which was closed with two layers (the 1st continuous and the 2nd inverted Lambert suture) using (vicryl 1). The rectus sheath was sutured using continuous absorbable sutures (vicryl 1), the skin was closed with a continuous subcuticular sutures (prolene). Operative time was recorded in minutes from skin incision to the last suture.

Postoperative evaluation:

After surgery, pain was measured by Visual Analog Scale (VAS) and for all participants with severe postoperative pain (VAS=7.5-10), medication intervention was performed according to the group classification. Patients administered group analgesics; 100 mg diclofenac suppository for group A, 1000 mg acetaminophen via intravenous infusion injection in 200 ml of 0.9 percent saline for group B, 100 mg diclofenac suppository and 500 mg intravenous acetaminophen for group C.

Postoperative pain was evaluated using (VAS) of 0-10 cm. Pain was classified into 4 categories: no pain (VAS=0-0.4), mild pain (VAS=0.5-4.4), moderate pain (VAS=4.5-7.4), and severe pain (VAS=7.5-10). Intensity and length of analgesia were assessed in patients with a VAS score in 0, 2, 4, 6, 12 and 24 hours after surgery.

Statistical analysis

Data entry and statistical analysis were performed using SPSS (Statistics Kit of Social Sciences) version 21 (SPSS Inc., Chicago, IL, USA) (Dean, 2006). Continuous, normally distributed data is expressed in mean and standard deviations. Quantitative data were analyzed by the Kolmogorov Smirnov data normality test. Independent sample t test (student t test) was used for regularly distributed results. The variance analysis (ANOVA) test was used for continuous multivariate data normally distributed. The Chi square test has been used to compare categorical data. Statistical significance was considered when the probability value (P) was less than or equal to 0.05.

RESULTS

This study showed that there was no significant difference between A, B, C groups with respect to age, weight, gestational age and parity as shown in table (1).

Table (2) and figures (1,2), showed there was no statistical significant difference between A,B,C groups with respect to oxygen saturation %, duration of surgery (minutes) and duration of anesthesia (minutes).

Table (3) showed that there was insignificant difference of pain before giving any analgesia between group A, B and C. Duration of analgesia is significantly higher in group C then group B, the least duration is detected in group A. There was significant difference of number of additional doses of analgesia which was higher in group A then group B and the least times detected at group C.

Table (4) and figure (3), showed a significant pain reduction in group C followed by group A in pain at 2h, 4h, 6h, 12h, 24h. Higher pain level is detected in group B Figure (3).

Table (1): Demographic characteristic of the study

Variables		Group A N=16	Group B N=16	Group C N=16	P
Age Mean ±SD		25.3±5.6	25.8±5.3	27.1±5.2	0.664
Weight(kg) mean ±SD		79.2±7.2	78.3±5.8	78.1±5.1	0.848
Gestational age (weeks) mean ±SD		38.5±1	38.1±0.6	38.1±0.9	0.281
Parity n (%)	P0	8(50)	6(37.5)	6(37.5)	0.583
	P1	4(25)	4(25)	5(31.3)	
	P2	3(18.8)	5(31.3)	4(25)	
	P3	1(6.3)	1(6.3)	1(6.3)	

P compare between 3 groups

Table (2): Comparison between A, B and C groups according to oxygen saturation %, duration of surgery (minutes) and duration of anesthesia (minutes)**.**

Variables	Group A N=16	Group B N=16	Group C N=16	P
oxygen saturation %	99.5±0.8	99.8±0.5	99.8±0.5	0.457
Duration of surgery(minutes)	41.1±3.3	40.3±3.4	42.8±3.3	0.111
Duration of anesthesia(minutes)	51.8±4	50.7±3.8	53.9±3.2	0.058

P compare between 3 groups.

Table (3): Comparison between group A, B and C regarding to pain score before analgesia, duration of analgesia and times of additional doses of analgesia.

Variable	Group A N=16	Group B N=16	Group C N=16	P
Pain before analgesia	5.9±0.7	5.9±0.5	6.4±0.5	0.154
Duration of analgesia (minutes)	206.8±9.6	405.8±6.9	991.4±12.4	**0.0001***
Times of additional doses of analgesia	3.7±0.4	1.5±0.5	1	**0.0001***

P compare between 3 groups

Table (4): Comparison between group A, B and C regarding postoperative pain recorded in the first 24 hour.

Variable	Group A N=16	Group B N=16	Group C N=16	P	P1	P2	P3
Pain 2h	3.8±0.8	4.8±0.7	**1.5±0.5**	**0.0001***	**0.01***	**0.0001***	**0.0001***
Pain 4h	4.8±0.8	6.1±0.7	**2.2±0.4**	**0.0001***	**0.0001***	**0.0001***	**0.0001***
Pain 6h	5.3±0.7	6.8±0.7	**2.8±0.6**	**0.0001***	**0.0001***	**0.0001***	**0.0001***
Pain 12h	4.2±0.6	5.7±1	**3.8±0.3**	**0.0001***	**0.0001***	**0.0001***	**0.035***
Pain 24h	3.1±0.4	3.6±0.6	**2.4±0.5**	**0.0001***	**0.006***	**0.0001***	**0.001***

P compare between 3 groups

Figure (1): Comparison between groups A, B, C. regarding to oxygen saturation %.

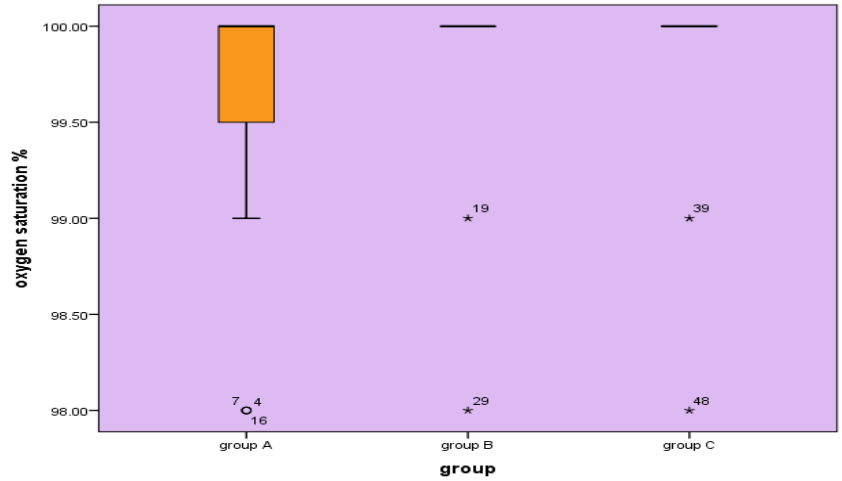


Figure (2): Comparison between group A, B, C. regarding to duration of surgery (minutes) and duration of anesthesia (minutes).

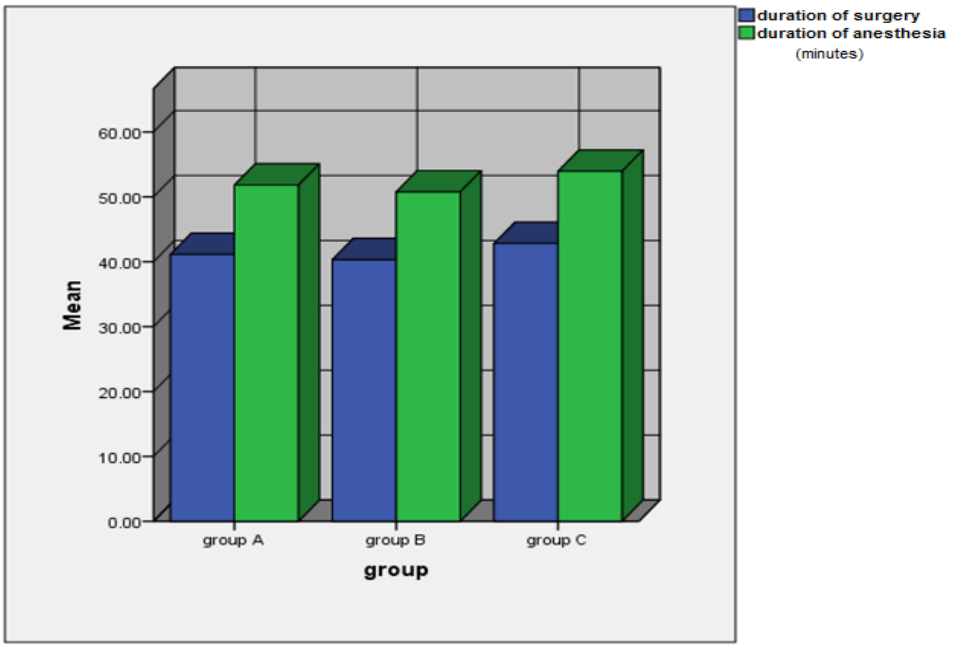
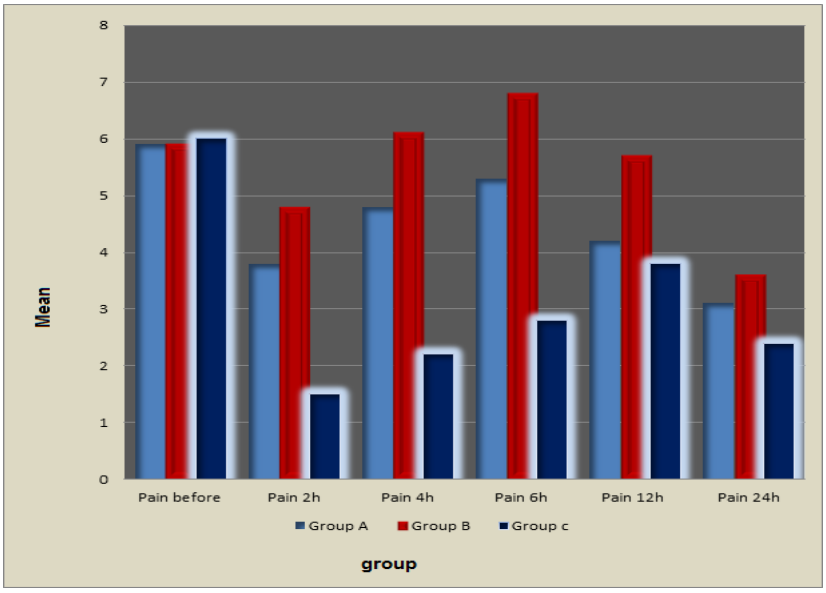


Figure (3): Pain assessment in groups A, B, C



DISCUSSION

Regarding the preoperative data in this study, there was no significant statistical difference between all groups as regard age, parity, weight and gestational age to ascertain that the postoperative outcomes will be related mainly to the selected procedure.

After proper evaluation, there was no statistical significant difference between A, B, C groups with respect to HR (Heart rate), SBP (Systolic blood pressure), DBP (Diastolic blood pressure), oxygen saturation %, operation time and anesthesia time.

There was insignificant difference of pain before giving any analgesia between

group A, B and C (5.9±0.7, 5.9±0.5, 6.4±0.5 respectively)

In this study there was significant statistical difference regarding pain reduction in group C as it was at 2h 1.5±0.5, at 4h 2.2±0.4, at 6h 2.8±0.6, at 12h 3.8±0.3 and at 24h was 2.4±0.5 followed by group A in pain which at 2h 3.8±0.8, at 4h 4.8±0.8, at 6h 5.3±0.7, at 12h 4.2±0.6 and at 24h 3.1±0.4.

Higher pain level is detected in group B which was at 2h 4.8±0.7, at 4h 6.1±0.7, at 6h 6.8±0.7 at 12h 5.7±1 and at 24h 3.6±0.6.

Duration of analgesia is significantly higher in group C (999.1±12.4minutes) then group B (405.8±6.9minutes), the least duration is detected in group A (206.8±9.6minutes).

We confirm our study by Bakhsha and his colleagues [10]significant effects of concomitant use of intravenous acetaminophen and diclofenac suppository on pain relief recorded (at 2h 1.47±0.71 , at 4h 2.33±1.03 , at 6h 3.23±1.71 , at 12h 3.76±1.9 and at 24h 2.5±0.94) and reducing the need for repeated doses of narcotics and prolonging the postoperative analgesia (988.0±96.71 minutes)

There was a substantial difference in mean pain intensity between the acetaminophen group and the combination group, as well as between the diclofenac and the combination group. In this study, the lowest mean pain severity was found in the combination group and the highest was observed in the diclofenac group (at 2h 4.33±1.6 , at 4h 5.93±1.14 , at 6h 6.67±1.18 , at 12h 6.4±1.19 and at 24h 3.8±1.13) [10].

The results showed the highest analgesia effect and the lowest need for analgesics was achieved by acetaminophen and diclofenac suppository combination, while the shortest period of analgesia (209.34±45.31 minutes) and the highest need for analgesics was found in the diclofenac community (additional dose times 3.13±0.21).

The length of analgesia in the combination group is 4.7 times that of the diclofenac group and 2.4 times that of the acetaminophen group. This disparity may be due to early onset and extended duration of acetaminophen-diclofenac combination analgesia relative to acetaminophen or diclofenac alone. Respectively, times of additional doses of analgesia reported significant difference which was high in group A (3.7±0.4) then group B (1.5±0.5) and the least times was detected at group C (1).

Studies by Romsing et al. have shown that the combination of acetaminophen and NSAID has better analgesia than acetaminophen alone and that the effect of a combination of NSAIDs is no better than a single form of NSAID [11].

Ong et al. also demonstrated that the use of a combination of acetaminophen and NSAID analgesics compared to the separate use of each medication was more effective [12].

The findings of other related research have demonstrated the efficacy of acetaminophen-diclofenac in postoperative pain relief in

postoperative patients compared to acetaminophen alone [13-15], which is consistent with our results. Munishankar et al., who analyzed 60 patients receiving analgesics who underwent abdominal gynecological surgery, were divided into three classes of paracetamol, diclofenac and their combination and the findings showed that demand for opioids in the paracetamol group was substantially higher than in the other two groups, while patients in the combination group experienced more successful analgesia. There was no substantial difference between the groups examined in terms of side effects [16].

The results of the study showed that postoperative intravenous paracetamol for tonsillectomy in adults with moderate to severe pain may improve rapidly. The intravenous paracetamol group varied substantially from the placebo group in terms of pain relief and median recovery time. Intravenous paracetamol greatly decreased the use of pethidine over a 24-hour span. The worst pain following surgery was also more severe in the placebo group than in the paracetamol group. There was no substantial difference in the occurrence of adverse outcomes between the groups. Intravenous paracetamol administered daily in adult patients with moderate to extreme pain following tonsillectomy offered rapid and successful analgesia and was well tolerated [17].

Akhavanakbari G et al analyzed 120 patients undergoing an elective caesarean section and the findings showed that in terms of pain severity and opioid use diclofenac and acetaminophen groups were substantially different from the control group while less morphine was used in diclofenac and paracetamol combination patients compared to paracetamol alone[18].

Mitra and his colleagues examined 204 women undergoing a caesarean section under spinal anesthesia with bupivacaine receiving 100 mg rectal suppository diclofenac plus either intravenous acetaminophen or postoperative tramadol. Diclofenac-tramadol and diclofenac-acetaminophen combinations will achieve adequate postoperative pain management in women undergoing caesarean section. Overall, the diclofenac-tramadol combination was more effective but associated with a higher rate of postoperative nausea.

In the meantime, several studies have shown that diclofenac alone is more effective in managing postoperative pain compared to acetaminophen alone. Results of Sidik et al., conducted in 80 patients undergoing scheduled caesarean section in 4 classes, placebo, rectal diclofenac, intravenous paracetamol and paracetamol-diclofenac combinations, showed lower scores of pain intensity and need for opioids in patients receiving diclofenac while acetaminophen was less effective than the combination of diclofenac-acetaminophen[19].

Nikooseresht et al [20] contrasted the results of diclofenac suppository and intravenous (IV) acetaminophen coupled with IV patient-controlled analgesia (PCA) for pain relief after laminectomy. Patient satisfaction levels were higher among those who received diclofenac compared to the acetaminophen community particularly at the time points of 6 and 12 h after surgery. The narcotic use of the PCA pump within 24 hours of surgery in the diclofenac community was substantially lower than that of the acetaminophen group.

Major surgical procedures, such as gastrectomy, result in extensive postoperative pain, which may lead to increased morbidity, distress and frustration among patients. The effects of the addition of diclofenac suppositories or intravenous paracetamol on morphine intake and on the consistency of post gastrectomy pain management were assessed in these patients. Intravenous paracetamol or diclofenac suppositories, administered for post gastrectomy pain management, reduced morphine intake by almost 32% and also increased alertness. However the number of opioids did not impact the rate of complications [21].

Some studies have shown that intravenous paracetamol stimulates the endogenic opioid receptor and thus has fewer adverse effects on the gastrointestinal tract, reduces platelet function and achieves an efficient concentration in a shorter period. Clinically speaking, paracetamol is well tolerated relative to other NSAIDs [22].

Due to its minimal side effects, NSAIDs are ideal for the treatment of moderate pain, while narcotics can be used to alleviate postoperative pain in acetaminophen treated patients and reduce the postoperative need for opioids [23].

The incidence and risk factors of diclofenac/acetaminophen combination as a single agent mediated Acute Kidney Injury (AKI) in postoperative pain relief as well as the average cost and duration of hospital stay for AKI and non-AKI patients were recently examined by Zhu [24]. The incidence of AKI-induced single agent diclofenac/acetaminophen in postoperative pain relief was 7.7%. Patients with hypertension or cirrhosis of the liver were more likely to develop AKI and the use of diclofenac/acetaminophen following surgery within 24 hours was a major risk factor for AKI. AKI has been prolonging the cost and time of hospitalization.

Although the mechanism of synergistic effects of this combination is still unclear, it is an effective option for therapeutic pain management [14].

Pressure relief is of considerable significance in patients with caesarean section delivery by calming the mother, improving the capacity of self-care, resulting in early discharge and consequently reducing nosocomial infections and hospitalization costs.

CONCLUSIONS

The combination of Acetaminophen and Diclofenac has stronger and longer analgesic effects than the single use of each drug. Based on our research results and previous related studies, it can be concluded that this combination is capable of providing sustained and efficient analgesia for postoperative caesarean section pain relief with fewer side effects and greater synergistic effects compared to other opioids, thereby decreasing the need for additional doses.

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