Original Article

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Post-Operative Analgesic Effects of Continuous Wound Infusion with Diclofenac Sodium and Bupivacaine Compared with Intramuscular Diclofenac Sodium and Bupivacaine Wound Infusion in Patients Undergoing Elective Caesarean Section

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Abstract

Context: Local anaesthetic injection into the wound is a simple way to relieve pain by direct inhibition of noxious impulses from the site of injury. Another approach to modulate peripheral nociceptive transmission is to reduce the local expression of mediators that sensitize nociceptors on afferent fibres by local administration of NSAIDs. *Aim:* Main aim of the study was to compare postoperative analgesic effects produced by wound infusion of diclofenac sodium and 0.125% bupivacaine mixture with intramuscular diclofenac sodium and 0.125% bupivacaine wound infusion in patients undergoing elective caesarean sections. *Settings and Design:* Prospective randomized comparative study. *Materials and Methods:* A prospective comparative study was conducted among 80 pregnant ladies of ASA1/ASA2 status undergoing elective caesarean section under spinal anaesthesia and was randomly allocated to 1 of 2 groups. *Group-1:* bupivacaine+diclofenac wound infusion (n=40); *Group-2:* bupivacaine wound infusion+ intramuscular diclofenac injection (n=40). Postoperative pain was assessed using VNS (verbal numeric scale). Patients with VNS score>4 received Inj. tramadol 50mg IM. VNS score was monitored on 1st,2nd,4th,6th,8th,12th,16th,20th and 24th post operative hours. *Statistical analysis:* Independent sample t test and Pearson's Chi-square test. *Results:* p=0.073 for total number of rescue analgesics requirement between two groups was statistically not significant but both groups were comparable in line and bar diagram for demographic data and VNS scores. *Conclusion:* Bupivacine with diclofenac wound infusion is a novel method of post caesarean analgesia sparring systemic diclofenac and opioid administration.

Keywords: Bupivacaine; Diclofenac; Wound Infusion; VNS.

Introduction

Pain is a complex but important protective phenomenon. It may be defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage [1]. Good postoperative pain relief is important as it alleviates patient's distress and helps in rapid uncomplicated recovery. It also reduces stress response to surgery, which is very important for patients with compromised cardiovascular or respiratory functions.

Postoperative pain mostly results from sensitization of afferent fibres at injury sites driving central sensitization. Recently, peripheral processes have gained attention as mechanisms of hyperalgesia, and prostaglandins are among highly sensitizing agents. To date, preoperative administration of a single local dose of non-steroidal anti-inflammatory drugs has shown inconclusive efficacy. Rather than a single bolus, the current study evaluates the postoperative analgesic effect of diclofenac by peripheral mechanisms by continuous intrawound infusion after elective caesarean delivery [2].

The anti nociceptive effect of non-steroidal anti-inflammatory drugs (NSAID's) mainly results from inhibition of cyclo-oxygenases involved in prostaglandin production [3]. Analgesia and antihyperalgesia from NSAID's after tissue injury involves both peripheral and central sites of action. For that reason, cyclo-oxygenase inhibitors are widely used during

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the postoperative period and have been the object of many studies. Several clinical trials have compared the analgesic efficacy of NSAID's given by different systemic routes, concluding that route has minimal effect for systemic administration [4]. In contrast, the anti-nociceptive effects after local administration of NSAID's at the site of injury are controversial in postoperative conditions, and specifically, the results from wound infiltration remain inconclusive [5]. However, it is worth noting that most of the trials regarding intrawound infiltration with NSAID's rely on administration of a single dose despite the fact that current knowledge about preoperative incisional pain emphasizes the need for an effective analgesia covering the entire preoperative period [6].

Bupivacaine wound infusion is widely recognized as a useful adjunct in a multimodal approach to postoperative pain management. Prolonged administration through a multi orifice catheter positioned by the surgeon at the end of the procedure increases the duration of action as compared with single injections and may there by improve the efficacy of local wound infiltration.[7] Continuous wound irrigation with a local anaesthetic has been used with success to provide effective analgesia after caesarean delivery [8, 9].

Local administration of NSAID's modulating peripheral nociceptive transmission by reducing the local expression of mediators that sensitize nociceptors on afferent fibres. Local administration reduces plasma concentration thereby the side effects [10, 11]. Local anaesthetic and NSAID infusions were of benefit as adjuncts to regional or general anaesthesia in caesarean delivery by reducing opioid consumption and improving pain relief [12].

Subjects and Methods

This study was conducted after obtaining departmental approval, approval from ethics committee and informed patient consent. Patients were allocated into one of the two groups (*bupivacaine+diclofenac group-1; bupivacaine group-2*) using computer generated random numbers.

All parturients were advised preoperative fasting for eight hours and premedicated with 50 mg intravenous ranitidine, 10 mg intravenous metoclopramide 30 minutes before surgery. After a 500 ml intravenous preload with balanced salt solution, a standardized intrathecal injection was performed in all parturients. With the patient in the left lateral position, a 25-gauge cutting spinal needle quinke type was inserted at the L3–L4 interspace and 2cc of 0.5% hyperbaric bupivacaine was injected. Thereafter, patients were positioned supine and all caesarean procedures were performed similarly through a Pfannenstiel incision and peritoneal closure.

On completion of surgery, under aseptic conditions, the surgeon placed a multi-hole 20-gauge catheter between unclosed parietal peritoneum and under surface of transeversalis fascia before its closure, along full length of the wound [13]. After skin closure infusion catheter is secured on the skin using sterile tape / plaster irrespective of group allotted.

Considering end of surgery as zero hour both the groups received bolus 20ml of 0.25% bupivacaine through wound infusion catheter.

Group 1: received continuous wound infusion with 123ml of 0.125% bupivacaine + 150mg diclofenac sodium at a rate of 5ml / hr using elastometric pump over 24 hrs.

Group 2: received 125ml 0.125% bupivacaine continuous wound infusion at 5ml / hr using elastomeric pump over 24hrs and Inj. diclofenac 75mg intramuscularly twice daily. Postoperative pain was assessed using VNS (verbal numeric scale).

Patients with VNS score >4 received Injection tramadol 50mg intramuscularly.

Adverse effects of treatments and other outcome parameters were also recorded, including occurrence of nausea, vomiting, and itching, using a categorical scoring system.

None	0
Mild	1
Severe	2

Nausea or vomiting is defined as nausea or vomiting score more than zero at any postoperative time point. Rescue antiemetic Injection Ondansetron 4mg IV was offered to any patient who experienced nausea or vomiting.

Sedation scores were assigned using University of Michigan Sedation Scale.

Awake and alert	*0*
Minimally sedated but easily aroused	*1*
Moderately sedated	*2*
Deep sleep	*3*
Unarousable	*4*

The presence of sedation is defined as sedation scores more than zero at any postoperative time point.

VNS score, nausea, vomiting, sedation and itching scores were monitored on 1st, 2nd, 4th, 6th, 8th, 12th, 16th, 20th and 24th post operative hours.

Close attention was given to the wound healing by both surgeons and nurses involved in postoperative care to detect any excessive inflammatory reaction or infection. Time for recovery in terms of days of hospital stay were recorded

Results

A total of 80 patients with 40 in each group were included in the study. Statistical analysis was performed using SPSS program.

Group 1: 123ml of 0.125%bupivacaine + 150mg diclofenac sodium continuous wound infusion.

Group 2: 125ml 0.125% bupivacaine continuous wound infusion and Inj., diclofenac 75mg intramuscularly twice daily.

Table 1: Demographic data and duration of surgery

Variable	Group 1	Group 2	p value
Age(yr)	26.1 ±3.6	25.9±3.9	0.23
Weight(kg)	54.4±5.5	55.3±6.6	0.50
Duration of surgery (min)	65.1±15.2	64.3±15.6	0.83

Fig. 1: Demographic data and duration of surgery

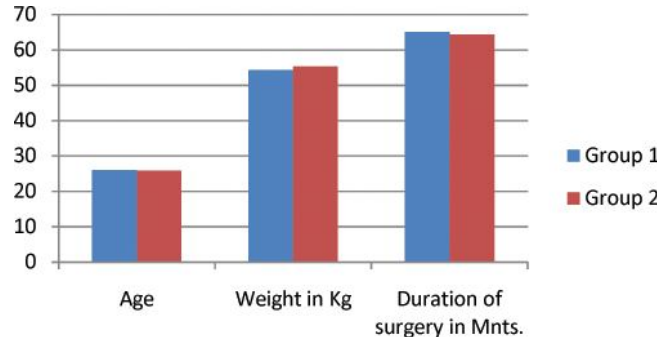
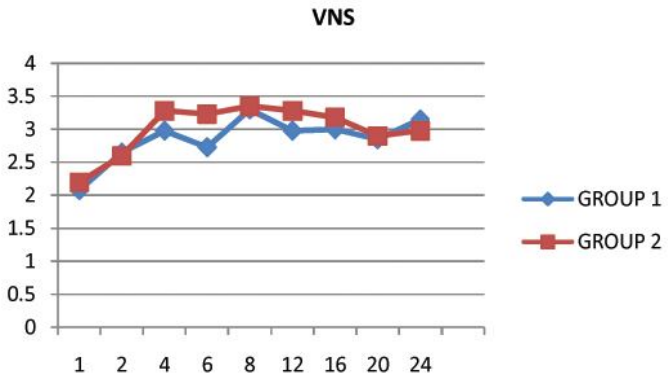


Table 2: Post operative VNS score

VNS score	Group 1	Group 2	P value
1st hr	2.0	2.2	0.41
2nd hr	2.6	2.6	0.80
4th hr	2.9	3.2	0.21
6th hr	2.7	3.2	0.03
8th hr	3.3	3.3	0.83
12th hr	2.9	3.2	0.17
16th hr	3.0	3.1	0.29
20th hr	2.8	2.9	0.76
24th hr	3.1	2.9	0.29

Post operative pain scores were found to be uniform over first 24 hours

Fig. 2: Post operative VNS score

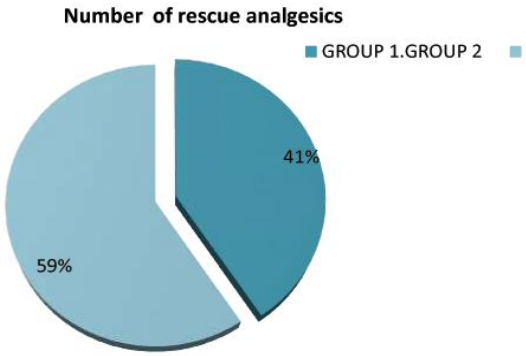


Data of age, weight, duration of surgery, pain scores, requirement of rescue analgesics, nausea and vomiting score were compared using independent sample t test. ASA status and side effects like sedation and itching were compared using Pearson Chi-square test.

Table 3: Number of rescue analgesics used

Rescue analgesics	Group 1	Group 2	P value
	0.50±0.51	0.73±0.59	1.81

Fig. 3: Number of rescue analgesics used



The patients in both groups were comparable with respect to age, weight, ASA status. The duration of surgery was also comparable between two groups.

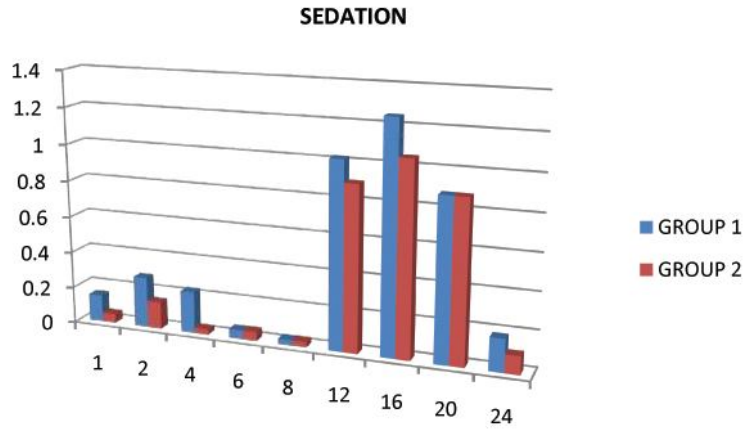
Post operative pain scores over 24 hours were analyzed using independent sample t test and p value was determined. Line diagram was constructed using mean VNS scores over 24 hours. VNS score was comparable between two groups as p value was consistently greater than 0.05.

Number of rescue analgesics used in both groups was compared with independent sample t test. P=0.073 was not statistically significant. Both groups were comparable with respect to requirement of rescue analgesics.

Table 4: Sedation score

Sedation Score	Group 1	Group 2	P value
1st hr	0.15	0.05	0.14
2nd hr	0.28	0.15	0.23
4th hr	0.23	0.03	0.02
6th hr	0.05	0.05	1.00
8th hr	0.03	0.03	1.00
12th hr	1.02	0.90	0.06
16th hr	1.25	1.05	0.15
20th hr	0.88	0.88	1.0
24th hr	0.18	0.10	0.34

Fig. 4: Sedation score



Sedation scores were comparable between two groups using independent samplet test over 24 hrs.

Table 5: Number of rescue anti-emitics

Rescue Anti-emitics	Group 1	Group 2	P value
	0.15±0.36	0.13±0.33	0.32

Group 1 received 41% and Group 2 received 59% of total number of rescue analgesics and is represented using pie chart. Rescue analgesic consumed was 18% less for Group 1 but p=0.073 was statistically not significant and there was no difference for requirement

Fig. 5: Number of rescue anti-emitics

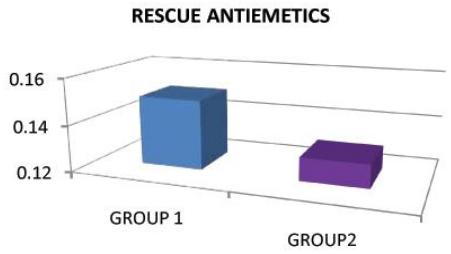
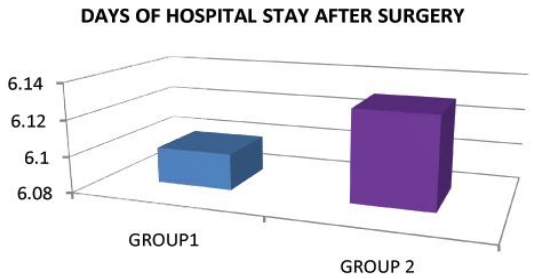


Fig. 6: Days of hospital stay



of rescue analgesics between two groups.

Group 1 and Group 2 were also comparable (p=0.175) with respect to number of rescue analgesics used when Pearson Chi-square test was applied.

Number of rescue anti-emitics used was comparable between two groups using independent sample t test. GROUP 1 had 6 and GROUP 2 had 5 incidences of nausea and vomiting. Side effect like itching was not observed in both groups.

The number of days of hospital stays between two groups recorded. P value was > 0.05 and considered not statistically significant difference; both groups were comparable with respect to number of days of hospital stay.

Discussion

Why has wound infusion analgesia become one of the accepted methods of post operative analgesia lately? It is easy to perform, effective and has high success rate. In our present study we have compared postoperative analgesic requirement between the two techniques namely continuous wound infusion with diclofenac sodium and bupivacaine and intramuscular diclofenac and bupivacaine wound infusion in patients undergoing elective caesarean sections.

In our case study, subjects were comparable in age, weight, duration of surgery and ASA status. 80 patients were studied, 40 received wound infusion with bupivacaine 0.125% and diclofenac sodium 150mg (125ml) over 24 hrs. Other 40 received bupivacaine 0.125% (125ml) wound infusion over 24 hrs and injection diclofenac sodium 75 mg intramuscularly twice daily. Pain was assessed using verbal numerical scale (VNS) score and was comparable between both groups as assessed by independent sample t test. p = 0.073 for post-operative rescue analgesic (tramadol) consumption between two groups was statistically not significant. Group 1 received 1000mg (41%) and Group 2 received 1300mg (59%) tramadol as rescue analgesic.

It was inferred that there was no significant difference between postoperative rescue analgesic requirements between two groups. Combining diclofenac with bupivacaine for wound infusion produced analgesia as effective as systemic diclofenac administration with bupivacaine wound infusion. There was no statistically significant difference between side effects between two groups. No complications related to wound catheter were reported and there was no difference in hospital stay between two groups.

Other studies on the subject shows similar observations with post operative opioid sparring effect.

Baig et al, showed less daily opioid requirements in patients with intra wound bupivacaine infusion and earlier ambulation, but no difference in overall pain scores and length of hospitalization after abdominal surgery with midline incision.

Particia M Lavand' Homme, MD, Fablenne Roelants, MD et al., studied 48hr continuous intra wound infusion with 240ml containing 300mg diclofenac, 0.2% ropivacaine or saline. The study concluded after caesarean delivery, continuous intrawound infusion of diclofenac demonstrates a greater opioid sparing effect and better postoperative analgesia than same dose administered as an intermittent intravenous bolus.

Bertoglio S, Fabiani F, Negri PD, Corcione A, Merlo DF, CafieroF et al, studied postoperative analgesic efficacy of preperitoneal continuous wound infusion compared to epidural continuous infusion with local anesthetics after colorectal cancer surgery. Concluded preperitoneal CWI (continuous wound infusion) analgesia with ropivacaine 0.2% continuous infusion at 10 mL/h during 48 hours after open CRC (colorectal surgery) surgery provided effective postoperative pain relief not inferior to CEI (continuous epidural infusion) analgesia.

Spencer S Liu, MD, Jeffrey M Richman, MD, Richard C Thirlby, MD, FACS, Christopher LWu, MD et al., did quantitative and qualitative systematic review of randomized control trials for efficacy of continuous wound catheters delivering local anesthetic for postoperative analgesia. In conclusion, both quantitative and qualitative systematic review identified the efficacy of continuous wound catheters with improved analgesia, reduced opioid use and side effects, increased patient satisfaction, and, perhaps, reduced hospital stay. The most notable feature was the consistent evidence of these benefits across a wide range of surgical procedures, location of wound catheters, and dosing regimens accompanied with low incidences of catheter-related complications. Both the efficacy and technical simplicity of this technique encourage its widespread clinical use.

Conclusion

Quality of analgesia was comparable in both groups with respect to pain scores and requirement of rescue analgesic. Postoperative analgesia produced by local diclofenac and bupivacaine infusion is as effective as local bupivacaine infusion with intramuscular diclofenac thereby avoiding systemic diclofenac administration. No significant side effects were exhibited by two groups. Wound infusion of diclofenac with local anesthetic is a novel and effective method that can be used as a part of multimodal analgesia in cases of laparotomy because of its efficacy and technical simplicity.

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