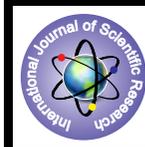


A Prospective, Double Blind, Controlled, Randomised Comparison of Rectal Versus Intravenous Diclofenac for Post Caesarean Section Pain



Medical Science

KEYWORDS : INTRAVENOUS DICLOFENAC, DICLOFENAC SUPPOSITORY, CAESEREAN SECTION, ANALGESIA

DR. APARNA ASHAY NERURKAR

DEPT OF ANAESTHESIOLOGY, 4TH FLOOR, COLLEGE BUILDING, LTMMC & LTMGH, SION, MUMBAI-400022

DR. JITENDRA SUBHASH DORKAR

Bharati Vidyapeeth Deemed University, Medical College & Hospital, Wanlesswadi, Sangli - Miraj Road, Sangli-416414

ABSTRACT

Aim: Comparison of rectal and intravenous (IV) Diclofenac with regards to duration and quality of analgesia, hemodynamic parameters and side effects for post Caesarean section pain. Materials and methods: A prospective, double blind, controlled, randomised study of 60 parturients undergoing Caesarean section under Subarachnoid Block. Patients received either Inj. Diclofenac 75mg intravenously or Diclofenac suppository 100 mg per rectally post operatively. Patients were assessed for 24 hours for their pain scores, rescue analgesic requirements, pain on coughing, tenderness, uterine pain, mobility scores, hemodynamic parameters and side effects, with tramadol being used as rescue analgesic. Statistical analysis involved unpaired students 't' test to compare all observations. Results: VAS scores and post operative mobility scores (p=0.03) were better for the first 4 hours with intravenous diclofenac while total tramadol consumption was slightly lower (p=0.019) in the rectal diclofenac group. Conclusion: Both routes of administration of diclofenac are acceptable for post Caesarean section analgesia.

Introduction:

Lower segment Cesarean section (LSCS) is commonly performed obstetric surgery. Management of post LSCS pain is challenging. This is usually achieved with opioids like tramadol etc. with side effects like decreased concentration, nausea and vomiting, respiratory failure and post-operative ileus. Diclofenac sodium, a NSAID decreases the inflammatory response, reduces peripheral nociception and can be safely used in breastfeeding mothers. Rectal suppositories of diclofenac are already in use for post LSCS pain relief.^{1,2,3,4,5} Intravenous preparations of diclofenac have also been used recently.^{6,7}

We therefore decided to compare rectal and intravenous (IV) diclofenac with regards to duration and quality of analgesia, hemodynamic parameters and side effects for post LSCS pain.

Materials and methods:

A sample size of 32 was required to show a 50 mg higher 24 hour tramadol requirement with intravenous diclofenac as compared to rectal diclofenac. We studied 60 patients to account for potential drop-outs and for better statistical analysis. Study was approved by institutional ethics committee and postgraduate review board. Written informed consent was obtained from all patients. Inclusion criteria were ASA Grade II parturients aged 18 to 35 years, undergoing LSCS under subarachnoid block (SAB). Complicated pregnancies, parturients having contra indications to SAB or allergy to local anaesthetics or diclofenac or Anorectal complaints were excluded. After standard preoperative assessment, all cases were conducted under SAB with 1.8 to 2.2 cc of 0.5% (Heavy) Bupivacaine intrathecally using routine theater protocol. Patients were withdrawn from study if there was high spinal, patients received analgesic supplementation or general anesthesia.

Thirty patients were assigned to each group randomly by chit block method. Group A received Inj. Diclofenac 75mg diluted in 100ml of (0.9%) NS intravenously at skin closure while Group B received Diclofenac suppository 100 mg per rectally post operatively prior to shifting patients out of operation theatre. After the administration of analgesic drug, the patients were observed for period of 24 hours postoperatively. (0 min., 30 min., 60 min., 90 min., 120 min., 150 min., 180 min., 4 hrs., 6hrs., 8 hrs., 12 hrs., 16 hrs., 20 hrs. & 24 hrs.) 0 min was when spinal level receded to T10 level by two segment regression method. The following parameters were observed by anaesthesiologist blinded to route of drug administration. Visual analogue scale scoring, pulse rate, blood pressure and side effects. Pain score more than four was considered significant and rescue analgesia with Inj. Tramadol 1 mg/kg intramuscularly was given. Quality of analgesia was determined by pain on coughing, tenderness, uterine pain. Mobility scoring was done as score of 1 when patient was comfortable on turning in bed, 2, 3 and 4 when patient complained of mild, moderate or severe pain on turning in bed respectively. Number of rescue analgesics and total amount of tramadol administered over period of 24 hrs. were noted in both groups. The incidence of side effects like nausea, vomiting, diarrhoea, gastritis, headache, skin reactions, sensitivity reactions were noted.

STATISTICAL ANALYSIS:

Statistical analysis involved use of student unpaired t test for comparison of demographic data, hemodynamics, VAS Scores, Qualitative data, Time for first dose of rescue analgesic and rescue analgesic requirement between groups.

OBSERVATIONS AND RESULTS:

We found comparable demographic profile of the patients in both the groups (group A Vs group B) in terms of age (24.50±3.21 yrs Vs 23.30±3.12 yrs), height (155.17±5.22 cm Vs 153.57±6.078 cm), weight (54.13±7.87 kg Vs 51.67±6.65 kg) and BMI (22.37±1.97 kg/m² Vs 21.83±1.64 kg/m²).

TABLE 1. PAIN AND MOBILITY SCORES

TIME	VAS SCORES			MOBILITY SCORES		
	GROUP A MEAN±SD	GROUP B MEAN±SD	'P' VALUE	GROUP A MEAN±SD	GROUP B MEAN±SD	'P' VALUE
0 HR	0.23±0.81	0.13±0.43	0.556			
½ HR	1.07±1.17	0.93±0.94	0.629			

1 HR	1.47±0.90	1.53±1.10	0.799			
1 ½ HR	1.77±0.72	1.80±0.66	0.854	2.73±0.51	2.80±0.61	0.651
2 HR	2.17±0.87	2.43±0.85	0.238	2.47±0.62	2.80±0.55	0.033
2 ½ HR	2.33±0.66	2.60±1.00	0.229	2.47±0.73	2.93±0.64	0.011
3 HR	2.50±0.90	2.57±0.85	0.77	2.57±0.67	2.70±0.79	0.487
4 HR	2.70±0.87	2.47±0.90	0.313	2.43±0.62	2.50±0.68	0.695
6 HR	2.77±1.00	2.20±0.84	0.02	2.37±0.61	2.13±0.34	0.075
8 HR	2.83±0.87	2.37±0.80	0.036	2.33±0.54	2.23±0.56	0.490
12 HR	3.07±0.94	3.13±1.10	0.803	2.17±0.64	2.47±0.50	0.051
16 HR	2.80±1.09	1.97±0.99	0.003	2.03±0.85	1.93±0.64	0.609
20 HR	3.13±1.04	2.73±1.25	0.185	2.03±0.66	1.83±0.87	0.324
24 HR	2.53±1.10	2.50±1.00	0.903	1.47±0.62	1.47±0.73	0.100

Table I suggests that VAS score in group A in the first 3 hours was less as compared to group B but it was not statistically significant. Group B had lower VAS score than group A after 4 hours of study with some of the readings showing statistical significance ($p < 0.003$). Postoperative mobility scores in group A were better during first 4 hours than group B ($p = 0.03$). It may be due to the fact that intravenous diclofenac has a faster onset and offset of action. Group B may have shown prolonged effect due to sustained levels of plasma concentration of diclofenac. Both the groups were comparable with respect to postoperative pain on coughing, on uterine contraction and tenderness; hemodynamic parameters and side effects.

TABLE II: RESCUE ANALGESIA

TIME OF FIRST RESCUE(MIN)	GROUP A	GROUP B	MEAN	'P'
	292±192.6	348±314.3	-56	0.40
TOTAL TRAMADOL REQUIRED (mg)			32.33	0.019

Group B required 32.33 mg of tramadol less as compared to group A which was statistically significant ($p = 0.019$). The reason for this tramadol sparing effect may be due to longer duration of action of diclofenac by rectal route than intravenous route.

DISCUSSION:

Post LSCS pain management is challenging and requires consideration of both mother and child. Diclofenac is useful in this respect due to opioid sparing property and safety in breastfeeding mothers. Administration of drugs by different routes alters the onset, duration and efficacy. In perioperative period, oral route is not feasible and causes gastric discomfort, nausea or vomiting, and intramuscular route is painful. Rectal diclofenac has been used as it is convenient to insert after subarachnoid block and gives longer duration of pain relief. Rectal administration may not be acceptable to all patients and may be associated with proctitis. Intravenous preparations of diclofenac have been recently used. To best of our knowledge, there are no studies comparing the intravenous route and rectal route of administration of diclofenac. Hence, after a review of literature, we decided to conduct a prospective, controlled, double blind comparison of the intravenous and rectal route of administration of diclofenac with regards to its duration of analgesia, quality of analgesia, hemodynamic parameters and side effects. We included 60 ASA II grade parturients between 18 to 35 years of age who underwent LSCS under SAB using routine theater protocol. Patients received either Inj. Diclofenac 75mg intravenously at skin closure or Diclofenac suppository 100 mg rectally post operatively prior to shifting out of operation theatre. Patients were assessed for 24 hours for their pain

scores, rescue analgesic requirements, pain on coughing, tenderness, uterine pain, mobility scores, hemodynamic parameters and side effects, with tramadol being used as rescue analgesic. Statistical analysis was performed using the unpaired students 't' test to compare all data.

We found that VAS scores and post operative mobility scores ($p = 0.03$) were better for the first 4 hours with intravenous diclofenac while total tramadol consumption was slightly lower in the rectal diclofenac group ($p = 0.019$). This may be because intravenous diclofenac has a faster onset and offset of action. The rectal diclofenac group may have shown prolonged effect due to sustained levels of plasma concentration. Both the groups were comparable with respect to postoperative pain on coughing, uterine contraction and tenderness; hemodynamic parameters and side effects.

The efficacy and opioid sparing effect of diclofenac with minimal side effects has been studied and various authors have found similar results. Sun et al⁸ in a double-blind, randomized study of epidural morphine and intramuscular diclofenac in postcesarean analgesia found no differences in overall pain relief or incidence of nausea, vomiting, pruritis, and bleeding. Luthman J et al⁵ showed a statistically significant reduction in total morphine consumption with single 100 mg diclofenac sodium suppository following elective LSCS performed under SAB. Sia et al⁴ in a 1997 study on 60 LSCS patients receiving morphine infusion 1.5 mg per hour postoperatively with or without 100 mg suppository diclofenac before surgical incision found better pain relief and more favorable scores for uterine cramping pain with diclofenac. Olofsson CI et al³ (2000) in a study of LSCS patients found that group receiving diclofenac rectally had 39% less consumption of ketobemidone. Lim et al² in a randomized double-blind study of forty-eight parturients scheduled for elective LSCS under regional anesthesia showed a 33% reduction of 24 hour opioid requirements with a 100 mg diclofenac suppository post-operatively. Zohar et al⁹ assessed the analgesic efficacy of diclofenac with or without bupivacaine wound instillation in LSCS with pfannenstiell incision. They found that similar postoperative analgesia in both groups. Surakarn et al¹⁰ demonstrated tramadol sparing effect of diclofenac 75 mg intramuscular in their 2009 study of 80 post LSCS patients performed under SAB. Joshi VS¹ in their study conducted in 2012 found Diclofenac to be a better alternative to tramadol in postoperative pain after Cesarean section as it is devoid of nausea and vomiting and has longer duration.

Thus both routes of administration of diclofenac are acceptable for post LSCS analgesia. Patient acceptance, administrative convenience, drug availability and anaesthetologist's preference may dictate the choice for route of administration.

REFERENCES

1. Joshi VS , Vyavahare RD , Khade Gh, et al. Comparative study of analgesic efficacy of rectal suppository of tramadol versus diclofenac in suppressing postoperative pain after Cesarean section. *International J. of Healthcare & Biomedical Research* 2013; 1(2): 32-7
2. Lim NL, Lo WK, Chong JL, Pan AX. Single dose diclofenac suppository reduces post-Cesarean PCEA requirements. *Can J Anaesth* 2001;48:383-6.
3. Olofsson CI, Legeby MH, Nygard EB, Ostman KM. Diclofenac in the treatment of pain after caesarean delivery. An opioid-saving strategy. *Eur J Obstet Gynecol Reprod Biol* 2000; 88:143-6.
4. Sia AT, Thomas E, Chong JL, Loo CC. Combination of suppository diclofenac and intravenous morphine infusion in post-caesarean section pain relief--a step towards balanced analgesia?. *Singapore Med J* 1997 Feb;38(2):68-70.
5. Luthman J, Kay NH, White JB. The morphine sparing effect of diclofenac sodium following caesarean section under spinal anaesthesia. *Int J Obstet Anesth* 1994;3: 82-6.
6. Thienthong S, Chongsomchai C, Kemthong W. A placebo-controlled, double-blind, randomized study of single-dose intravenous diclofenac for pain relief after a cesarean section. *Acta Anaesthesiol Taiwan*. 2012 Dec;50(4):150-2.
7. Campbell WI, Kendrick R, Patterson C. Intravenous diclofenac sodium. Does its administration before operation suppress postoperative pain? *Anaesthesia*. 1990 ;45(9):763-6
8. Sun HL, Wu CC, Lin MS, Chang CF. Effects of epidural morphine and intramuscular diclofenac combination in postcesarean analgesia: a dose-range study. *Anesth Analg* 1993 Feb;76(2):284-8.
9. Zohar E, Shapiro A, Eidinov A, et al. Postcesarean analgesia: the efficacy of bupivacaine wound instillation with and without supplemental diclofenac. *J clin anesth* 2006;18(6):415-21.
10. Surakarn J, Tannirandorn Y. Intramuscular Diclofenac for Analgesia after Cesarean Delivery: A Randomized Controlled Trial. *J Med Assoc Thai* 2009;92(6):733-8