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ORIGINAL ARTICLE

ROPIVACAINE CONTINUOUS WOUND INFUSION VERSUS CONTINUOUS EPIDURAL VERSUS SYSTEMIC ANALGESIA FOR POST CAESAREAN DELIVERY UNDER SPINAL ANAESTHESIA: A PROSPECTIVE RANDOMISED CONTROLLED STUDY

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ABSTRACT: BACKGROUND: Opioid based analgesic regimens have been the gold standard for post caesarean analgesia until recently. Regional techniques like local intra-wound infusion techniques are becoming popular now. Our aim is to evaluate the efficacy of 0.2% Ropivacaine continuous wound infusion versus continuous epidural versus conventional systemic analgesia for post caesarean delivery. **METHODOLOGY:** 60 healthy parturients of ASA I/II were randomized after elective caesarean section into 3 groups of 20 each. Group-A: Received 0.2% Ropivacaine via an epidural catheter placed into subcutaneous tissue and fascia before skin closure at the rate of 5ml/hr. through infusion pump. Group-B: Received 0.2% Ropivacaine continuous epidural infusion via an epidural catheter at the rate of 8ml/hr. An initial bolus of 10ml was given in groups A&B. Group-C: Received standard systemic analgesia with diclofenac sodium and rescue opioid. Post operatively parturients were assessed for VAS scores for pain at rest and during movement, total Ropivacaine consumption, Tramadol consumption and side effects. Data were analyzed using SPSS software version 22. **RESULTS:** There were no significant differences in the mean VAS scores at rest and at movement between groups A or B and C. The consumption of Tramadol was significantly greater in Group C (p value AC=0.025, BC=0.0000) than A or B. Mean Ropivacaine consumption is significantly higher in Group B (p=0.000) than Group A. **CONCLUSION:** Continuous local intra-wound analgesia with Ropivacaine produced comparable analgesia to that of continuous epidural and superior analgesia compared to standard systemic analgesia.

KEYWORDS: Continuous wound infusion, Continuous epidural, Ropivacaine, Post caesarean analgesia.

INTRODUCTION: Today's strategy regarding post-caesarean analgesia is multimodal analgesia, which is rapidly becoming the standard of care as it produces effective analgesia with minimal side effects.[1] The benefits of adequate post-operative analgesia include a reduction in the post-operative stress response, reduction in morbidity, early ambulation, promotes interaction between mother and child, helps in breast feeding and also decreases chronic persistent post-caesarean pain.[2,3] The potential benefits of regional techniques include opioid sparing and their related side effects with improved patient comfort.[4]

Recently continuous wound analgesia techniques are gaining interest as analgesia can be extended for prolonged post-operative periods using a multi holed wound catheters or epidural catheters.[5, 6] Continuous local anesthetic infusion into the surgical wound relieves pain by direct inhibition of noxious afferent generator potentials from peripheral nerve fibres and attenuation of

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local inflammatory response to injury.[7-9] It is important to add NSAIDS for synergistic or additive analgesia. The anti-inflammatory and antipyretic properties of NSAIDS may reduce visceral pain originating from uterus, complementing somatic pain relief from opioid.[10-12] NSAIDS like paracetamol, diclofenac, ketorolac, ketoprofen etc., have been used in several studies.[13-15]

AIM: The aim of our study is to evaluate the efficacy of 0.2% Ropivacaine continuous wound infusion versus 0.2% Ropivacaine continuous epidural versus conventional systemic analgesia in healthy parturients posted for caesarean section.

MATERIALS & METHODS: After institutional ethics committee approval & written informed consent, 60 healthy parturients of ASA grade I/II were randomized after elective caesarean section into 3 groups of 20 each. Randomization was done using computer generated random number tables.

Inclusion Criteria:

- Age - 18-45 yrs.
- ASA - I/II.
- Wt - 45-80kgs.
- Height - 146-160cms.
- Patients not using medications which have effect on pain perception.
- Gestational age 37-40 weeks.

Exclusion Criteria: Parturient refusal to participate, any contraindications to central neuraxial block, history of allergy to study drugs (Bupivacaine, Ropivacaine, Tramadol, Diclofenac). All parturients underwent lower segment caesarean section through a Pfannenstiel incision under standard spinal anesthesia with Bupivacaine 0.5% (1.8 to 2cc) heavy at L_2/L_3 interspace. Parturients of group A received 0.2% Ropivacaine continuous wound infusion through an 18 G multiholed epidural catheter (B Braun, Germany) which was placed below the fascia of rectus sheath such that the tip was sited at the point that demarcated 50% of the length of the surgical wound, before skin closure.

The catheter was tunneled subcutaneously and sutured to the skin. There after the catheter was connected to a syringe pump and infusion was started at the rate of 5ml/hr, after an initial bolus of 10ml. Parturients of Group B received 0.2% Ropivacaine continuous epidural infusion through an 18G epidural catheter at a rate of 8ml/hr, after an initial bolus of 10ml.18G epidural catheter was instituted at L_1/L_2 interspace (before giving spinal anesthetic at L_2/L_3 interspace) and 4cm of catheter was advanced into epidural space.

Parturients of Group C received conventional systemic analgesia with intramuscular diclofenac sodium and intravenous Tramadol. As a part of multimodal analgesic regimen 75mg of intramuscular diclofenac sodium was given immediately after surgery and 12th hrly there-after in all the three groups. Post operatively wound infusions and epidural infusions were started when parturients demanded analgesia (VAS > 4) in the immediate post-operative period. In Group C, first dose of intravenous Tramadol was given on demand (VAS > 4) in the immediate post-operative period. Group C served as the control group.

Post-operatively all the parturients were monitored for pain using Visual Analogue scale (0-10cm) superimposed by Numerical rating scale at rest and also during straight leg raising movement,

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consumption of Tramadol, side effects, total Ropivacaine consumption and early ambulation. Post-operative analgesic regimen was to titrate the rate of infusion to the analgesic need by an increment of 2ml/hr. in groups A and B if the VAS score > 4 for two successive hours. Assessments were made at 2, 6, 12 and 24 hrs. by an observer blinded to group allocation and the study drug using a standard questionnaire.

Additional request for analgesia even after increasing the rate of infusion was supplemented by a bolus dose of Tramadol 1mg/kg intravenously in all the three groups. Degree of motor blockade was assessed using Modified Bromage score in all the parturients. Ondansetron 4mg IV was given as rescue anti emetic for post-operative nausea and vomiting. Sedation was assessed with five point rating scale (0 = fully alert, 1 = sleepy but aroused with verbal stimulation, 2 = sleepy but aroused with light touch, 3 = sleepy but aroused with pain, and 4 = unconscious patient).

Statistical Analysis: Data was analyzed using SPSS software version 22. Demographic data was assessed using Fischer's Exact Text. VAS (Visual Analogue Scale) Scores at specific time intervals were assessed using student-'t'-test. Mean opioid consumption and mean Ropivacaine consumption was assessed using independent sample-'t-test. Categorical data was assessed using chi square test. Data was represented as mean + standard deviation. $p < 0.05$ was considered statistically significant.

RESULTS: 60 parturients were enrolled for the study, 55 patients completed the study. Two parturients in Group A were excluded due to severe gastritis and cough in the next morning respectively. Two parturients of Group B were excluded from the study due to patchy epidural and technical failure of syringe pump respectively. One parturient of Group C was excluded due to conversion of spinal into general anesthesia because of inadequate spinal blockade. Analysis of demographic data showed that they were comparable in all the groups (table: 1).

The mean VAS scores for pain during rest and movement were comparable between groups A and B at all specified time points, but they were slightly lower in the epidural group. (Statistically not significant). The mean VAS scores for pain during rest and movement were significantly higher in Group C, when compared with Group A or Group B at all specified time points (P = 0.000, statistically highly significant) (table:2 and table:3).

The mean consumption of Tramadol over 1st 24 hrs. between Groups A and B, was comparable (P = 0.06, statistically not significant) (table: 4). The mean consumption of Tramadol was significantly higher in Group C, when compared to Group A or Group B. (AC p = 0.025, BC p = 0.000, statistically highly significant) (table: 4).

The mean consumption of Ropivacaine was significantly higher in Group B, when compared to Group A over first 24 hour period (A = 137.1 + 22.07 ml Vs. B = 179.77 +25.2 ml) (p=0.000) (table: 5). The mean rate of infusion of Ropivacaine was 5.7ml/hr. in Group A compared to 7.8 ml/hr. in Group B. Four parturients of Group A required additional 2ml/hr. of 0.2% Ropivacaine infusion to achieve satisfactory analgesia.

Two parturients of Group B required additional 2ml/hr. of 0.2% Ropivacaine infusion to achieve satisfactory analgesia. Four parturients of Group A required a bolus dose of Tramadol 1mg/kg IV as they had uterine cramps (VAS > 4). Only one parturient of Group B required a bolus dose of Tramadol, when VAS score was > 4.

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In the above parturients bolus doses of Tramadol were given when VAS > 4 even after increasing the infusion rates by 2ml/hr. for two successive hours. In six parturients of Group B, the infusion rate was decreased by 2ml/hr. as the systolic blood pressure was dropped to 80mmhg (> 20% from baseline). Two parturients had unilateral motor blockade and four parturients had bilateral motor blockade in Group B (Modified Bromage Score = 1).

The incidence of hypotension and motor blockade were significantly higher in Group B than Group A or Group C (p = 0.001) (Table: 6). The incidence of nausea and vomiting was significantly higher in Group C than Group A or Group B, which is statistically significant. (A = 11.1% Vs. B = 16.6% Vs. C = 42.1% [p = 0.046]) (Table: 6). There were no significant differences in the incidence of shivering between the three groups (Table: 6).

The incidence of sedation was significantly high in control group (Sedation score 1). There were no reports of delayed wound healing or wound infections in our study. No signs of Ropivacaine toxicity were observed in Groups A or B.

DISCUSSION: Acute post-operative pain ranks high among the potential anesthesia outcomes after caesarean delivery. Optimal analgesia regimens should incorporate multimodal strategy which employs different agents that work through different mechanisms minimizing reliance on opioids and less side effects with great patient comfort.[16] Continuous administration of local anesthetics at the surgical site via wound catheters would be the most rational approach to reduce the afferent nociceptive stimuli and there by pain and stress response.[17]

NSAIDS have been the standard adjuncts for post caesarean analgesia as they combat the inflammatory components of pain emanating from the uterus as well as the nociceptive components originating from incision site.[18] Our study demonstrates that continuous wound infusion of Ropivacaine for caesarean section provides adequate and satisfactory analgesia and a safer alternative to epidural technique with minimal side effects.

In our study, we used a multi-orifice epidural catheter which is placed subfascially and tunneled beneath the skin to deliver the local anesthetic. Infusions can be delivered from 24 to 72hrs through dedicated pumps. The efficacy of this technique also depends upon the type, length, position (subfascial/subcutaneous) of the catheters, duration of LA infusion and the type of surgery.[19] Recently several randomized control trials have reported the efficacy and safety of wound infusion techniques.[20] Ranta PO, Ala-kokko et al. reported in their study that 0.125% epidural bupivacaine was associated with lower pain scores when compared to 0.25% bupivacaine administered through a subfascial wound infusion catheter for post caesarean delivery.[21]

Here, they administered the drug as intermittent boluses. According to Fredman B, Shapiro A et al. who evaluated the analgesic efficacy of patient controlled Ropivacaine instillation after caesarean delivery reported that it is a simple technique that provides safe and effective analgesia.[22] In this study they also used epidural catheters for wound infusions as we did in our study. In a recent clinical trial conducted by O Neill, Patricia MD et al who compared continuous 0.2% Ropivacaine wound instillation versus epidural morphine for post caesarean delivery reported that wound infusion provided better analgesia with few side effects than intermittent epidural morphine analgesia.[23] The results of this study correlated with the observations of our study.

In a randomized clinical trial by Rackelboom T, Lestrat S, et al, continuous wound infusion over 48 hours with Ropivacaine and ketoprofene through a multi holed catheter inserted below the

fascia resulted in better analgesia when compared with administration of local anesthetic above the fascia.[24] Anil Gupta and Andrea Perniola et al, conducted a randomized double blind comparison between placebo and local anesthetic infused intraperitoneally and demonstrated significantly smaller opioid consumption with Levobupivacaine infused intraperitoneally after abdominal hysterectomy.[25]

Spencer S, Liu, MD, Jeffery M Richman, MD et al; conducted a systematic review of randomized trials to determine the efficacy of continuous wound catheters delivering local anesthetic and reported that most of the RCTS demonstrated minimal side effects and patient satisfaction with lower pain scores especially in gynecologic and urologic surgeries.[26] The results of most of the randomized clinical trials were consistent with the observations of an study.[27-29]

Our study has certain limitations. Firstly, patients and the observer who did post-operative assessments were not blinded to the technique though they were blinded to study drug. Secondly, the plasma concentrations of Ropivacaine were not assessed. Ropivacaine is a safer drug with low toxicity profile and its efficacy was proved in many clinical trials.[30]

Ropivacaine toxicity was not reported in our study. Many further studies are awaited to determine the optimal infusion doses and the cost benefit analysis of wound infusion techniques. Tilleul P, Aissou M, et al; underwent cost- benefit analysis comparing epidural IV PCA with morphine and continuous LIA for post-operative pain after abdominal hysterectomy and concluded that continuous wound infusion technique is less costly and almost equivalent efficacy than epidural analgesia.[31]

Current evidence indicates that wound infusion techniques were not superior to epidural analgesia but remains a valuable option for clinical scenarios, where epidural analgesia is contraindicated or technically impossible or poorly tolerated. Our study showed that continuous wound infusion of 0.2% Ropivacaine provided comparable analgesia, no side effects, opioid sparing, less Ropivacaine consumption and is technically simple when compared to continuous epidural.

CONCLUSION: Ropivacaine continuous wound infusion provides almost equivalent analgesia comparable to continuous epidural and superior analgesia when compared to systemic analgesia and a promising alternative to more invasive neuraxial techniques for post caesarean delivery.

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	A (Incisional) (n=18)	B (Epidural) (n=18)	C (Control) (N=19)	P value*
Age in years	22.78+2.9	22.2+2.02	22.4+1.8	p=0.398
Height in cms	150+4.5	148.4+2.5	149.17+4.5	p=0.358
Weight in kgs	58+9.8	57.5+7.9	58.7+9.4	p=0.064
Gestational Age (weeks)	37.7+0.42	37.7+0.48	37.8+0.38	p=0.284
Duration of Surgery (in min.)	50.4+9.36	47.3+12.05	40.17+7.921	p=0.081
ASA status I/II	10/8	12/6	10/9	
Level of Sensory Block	T_6+1	T_6+1	T_6+1	

Table 1: Demographic Data

Data expressed as mean (SD) or absolute numbers

*Fischer's exact test

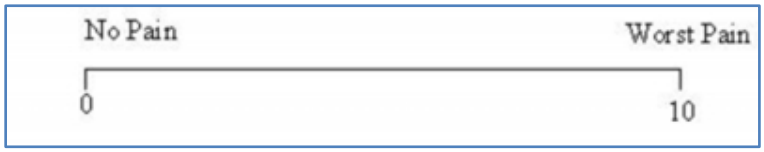

Figure 1: VAS=Visual Analogue Scale

Time (Hours)	A (Incisional) (n=18)	B (Epidural) (n=18)	C (Control) (N=19)	p value*
2	2.17+1.339	1.44+0.856	5.26+1.485	p=0.000
6	2.33+1.372	1.44+0.92	4.05+1.393	p=0.000
12	2.22+1.592	1.61+1.145	2.42+0.692	p=0.000
24	1.56+1.149	1.11+0.758	2.58+0.692	p=0.000

Table 2: VAS Scores at Rest

*student-t-test

p value <0.05 statistically highly significant

SD- Standard Deviation

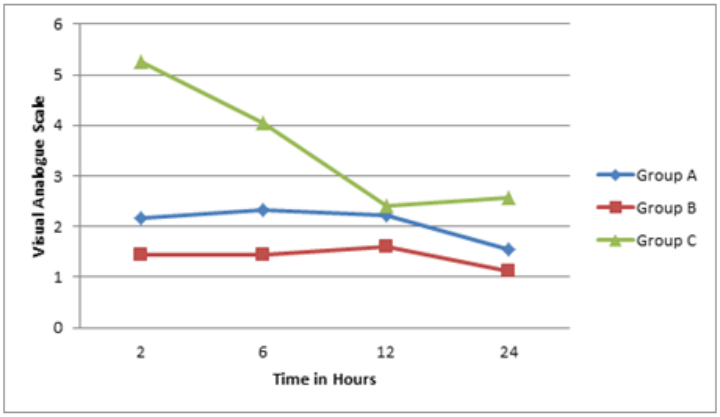

Figure 2: Mean VAS scores at rest

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Time (Hours)	A (Incisional) (n=18)	B (Epidural) (n=18)	C (Control) (N=19)	p value*
2	2.78+1.478	1.94+1.110	6+1.795	p=0.000
6	3+1.18	2.28+1.07	4.74+1.24	p=0.000
12	2.67+1.49	2.22+1.003	3.16+0.688	p=0.000
24	1.89+1.07	1.5+0.857	2.95+0.621	p=0.000

Table 3: VAS Scores at Movement

*student-t-test
p value <0.05 statistically highly significant
SD- Standard Deviation

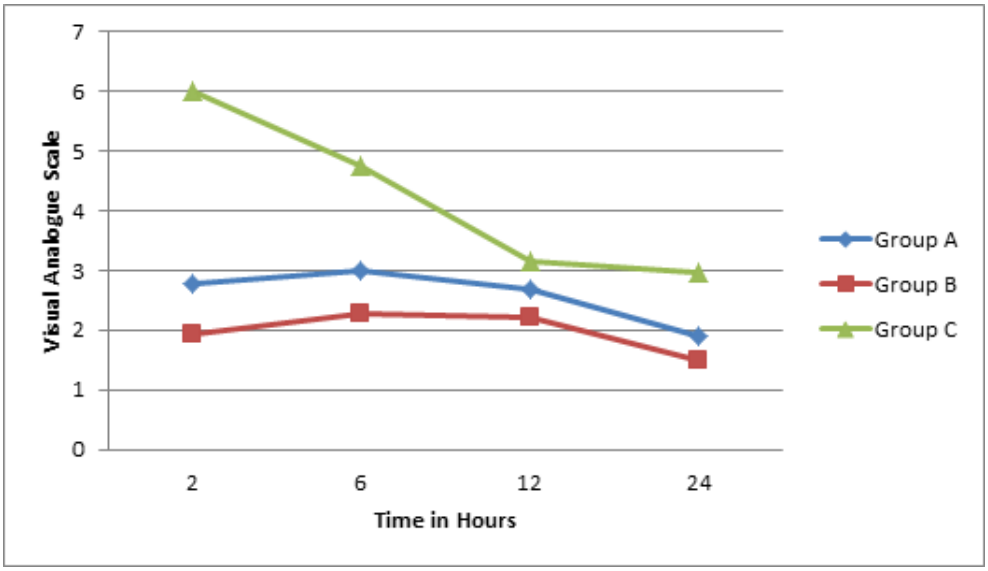

Figure 3: Mean VAS scores at movement

	Mean	SD	p value*
Group AB	17.56	29.35	0.06 (NS)
Group AC	112.44	80.83	0.025 (HS)
Group BC	130.0	60.90	0.000 (HS)

Table 4: Mean Tramadol Consumption (0-24hrs)

* Independent sample 't' test

SD= Standard Deviation
NS= Not Significant
HS= Highly Significant

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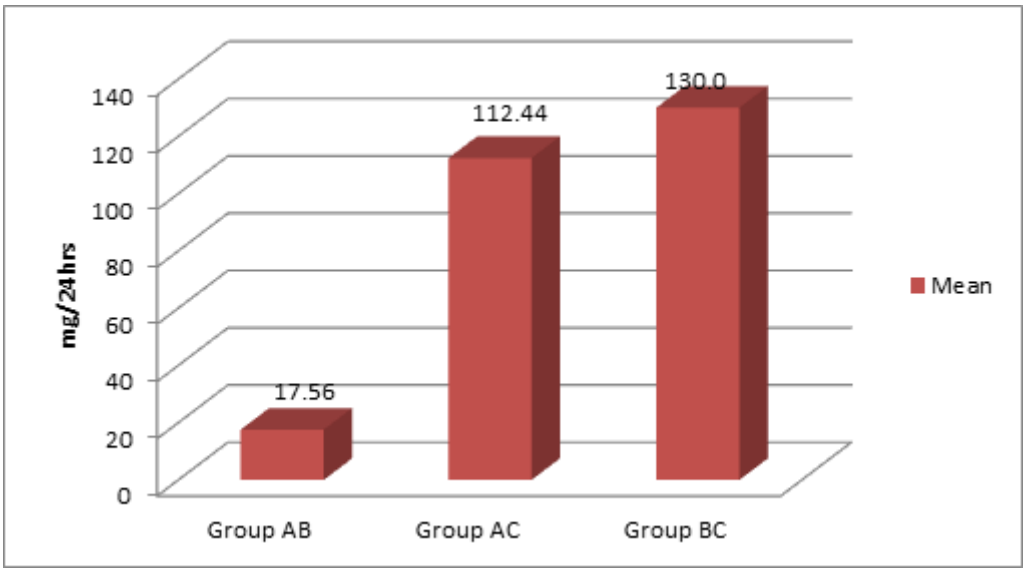

Figure 4: Mean Tramadol Consumption (0-24hrs)

	Mean	SD	p value*
A (Incisional)	137.1	22.07	0.000 (HS)
B (Epidural)	179.77	25.2	

Table 5: Mean Ropivacaine Consumption (ml/24hrs)

* Independent sample 't' test
SD= Standard Deviation
HS= Highly Significant

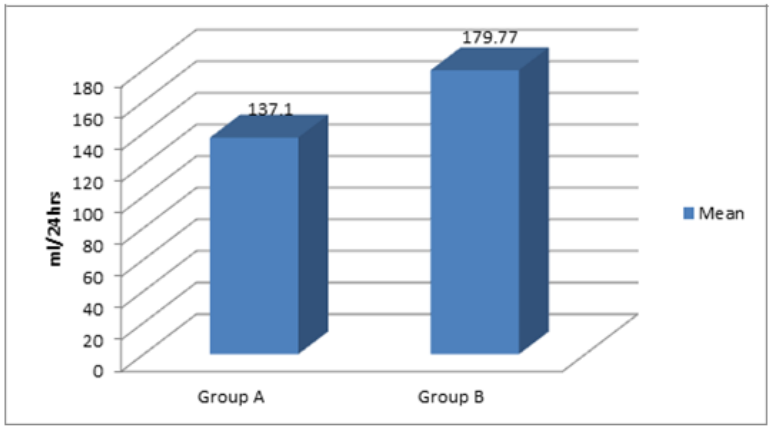

Figure 5: Mean Ropivacaine Consumption (ml/24hrs)

A (Incisional)
B (Epidural)

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	A (Incisional) (n=18)	B (Epidural) (n=18)	C (Control) (n=19)	X^2	p value*
Nausea and Vomiting	2 (11.1%)	3 (16.6%)	8 (42.2%)	6.178	0.046
Hypotension	-	6 (33.3%)	-	13.412	0.000
Shivering	2 (11.1%)	4 (21.05%)	3 (16.6%)	0.792	0.673
Sedation	-	-	5 (26.3%)	10.962	0.004
Motor blockade	-	6 (33.3%)	-	15.96	0.0001

Table 6: Comparison of side effects between groups

* Chi square test

Data expressed as absolute numbers and percentage
$p<0.05$ statistically significant

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