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**Research Article**

# A COMPARATIVE STUDY OF CLONIDINE AND FENTANYL CAUDAL AMBULATORY ANAESTHESIA WITH ROPIVACAINE IN ANO-RECTAL SURGERY

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**A R T I C L E I N F O**

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**A B S T R A C T**

**Background:** Caudal anesthesia is one of the best options for perineal surgery. Ambulatory procedures requires caudal anesthetic methods permitting patients to be discharged shortly after surgery. In this study we aimed to evaluating the clonidine and fentanyl with ropivacaine in caudal epidural block for anorectal ambulatory surgeries.

**Methods:** Total ninety adult patients were randomized into three groups in a double-blinded as: group R: ropivacaine 0.5% with normal saline, group RC: ropivacaine 0.5% + 25µg clonidine and group RF: ropivacaine 0.5% + 25µg fentanyl. Patients were examined for motor block, sensory block, and block duration. Parametric data were analysed using ANOVA test. Non parametric data were analysed with chi square test.

**Results:** The demographic data were comparable with respect to age, BMI, sex, and ASA status in all groups. Moreover, there was no significant difference in the type of surgery and duration of surgery. Hyperbaric ropivacaine and fentanyl produced similar block characteristics in all three groups. Hemodynamic parameters were stable throughout the surgery in groups R, group RC and group RF. The time of first rescue analgesia were significantly different ($p<0.05$) in between inter-group and group R and group RF.

**Conclusions:** In this prospective study, small-dose ropivacaine with clonidine was as effective as small-dose ropivacaine with fentanyl for anorectal procedures in the ambulatory procedure.



## INTRODUCTION

Outpatient surgery offers a number of advantages for both the patients and the healthcare system. The percentage of minor surgery carried out on an outpatient basis has increased rapidly in recent years (Wong *et al*., 2004).Many of ano-rectal surgeries such as Fistulectomy, Hemorrhoidectomy, and Sphincterotomy are now performed as day care surgeries (Siddiqui *et al*., 2007).

Caudal epidural block is one of the most popular, reliable, and safe techniques. In recent years, ropivacaine has increasingly replaced bupivacaine for regional Anaesthesia because of its similar analgesic properties, lesser motor blockade and decreased propensity of cardiotoxicity (Arthur *et al*., 1988; Scott *et al*., 1989). Though a slightly larger dose of ropivacaine is required as compared to bupivacaine to achieve the analgesic and anaesthetic effects (Klein *et al*., 1998). The addition of an adjuvant such as Opioids, Alfa-agonist can decrease the dose of ropivacaine required, thereby eliminating quite a few side effects associated with larger doses of ropivacaine (Bajwa *et al*., 10a; Ahirwar *et al*., 2014; Faria-Silva *et al*., 2016).

Fentanyl is the substantiagelatinosa in the dorsal horn of spinal cord, where it blocks the neural fibers carrying pain impulses both at pre-synaptic and post synaptic levels. Addition of opioid to local anesthetics gives the opportunity to use more diluted local anaesthetic solutions for better analgesia, and reduces systemic toxicity risk and motor block incidence of local anesthetics (Madhusudhana *et al*., 2011).

Clonidine is an alpha-2 adrenoceptor agonist which was widely used as an antihypertensive, sedation, premedication and adjutant analgesic. Clonidine as an adjuvant has allowed the use of lower concentration of the local anaesthetic for achieving the same level of anaesthesia but with a prolonged duration of analgesia which increases the margin of safety and reduces the incidence of unwanted motor blockades (Gabriel *et al*., 2001).

However, data regarding caudal epidural block in adult ambulatory surgery are scarce. Purpose of this study to find out an anaesthetic technique for outpatient ano-rectal surgeries that provides excellent operating conditions, absence of

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adverse events, high patient acceptance, and rapid patient recovery and discharge. Therefore, we aim to evaluate the effects of clonidine and fentanyl with ropivacaine in single shot caudal epidural block for anorectal ambulatory surgeries.

## MATERIALS AND METHODS

After institutional ethical approval (No. ECR/262/inst/UP/2013), this prospective randomized study was carried in between period of January to December 2016. Informed consent was taken from all patients/Relative, who were recruited for study. Patients aged 18-70 years, either sex, ASA physical status I or II and planned for ano-rectal day care surgeries for conditions such as hemorrhoids, fistula in ano, fissure, and examination under anaesthesia were included in the study. The patients recently given chemotherapy, cardiovascular diseases, use of β blocker and ACE inhibitor, ASA III and IV, severe pulmonary diseases, chronic pain syndrome and inability to communicate with the patient due to any reason were excluded from the study.

All recruited 90 patients underwent pre-anaesthetic check-up and investigation as per institutional protocol. Anxiolysis and aspiration prophylaxis were given night before and morning of surgery as per routine. On the day of surgery, 18 G IV cannula were secured and base line vitals (pulse rate, BP, ECG, SpO2) were noted. All patients received inj. midazolam 1-2 mg IV as anxiolytic before procedure. Patients were assigned to one of the following three treatment groups in a double-blinded fashion by sealed envelope method. Patients were randomized into three groups (*n*=30 each) using a computer generated random number tables. These groups were further classified, based on the caudal block anaesthetics drug combination used.

- Group R: Patients who received (13.5ml) ropivacaine 0.5% with (0.5ml)normal saline
- Group RC: Patients who received (13.5ml) ropivacaine 0.5% + 25µg (0.5ml)Clonidine
- Group RF: Patients who received (13.5ml) ropivacaine 0.5% + 25µg (0.5ml)Fentanyl

All patients were made in the lateral position (Sims's position). The skin of the sacrococcygeal area was thoroughly prepared with povidoneiodine. Once the sacral hiatus was identified with non-dominant hand, a short bevelled 23-gauge needle was then inserted at 45 degree or less till a "Pop" was felt as the sacrococcygeal ligament was pierced. The needle was advanced approximately 2 to 3 mm more. After negative aspiration in all quadrant to exclude accidental intrathecal or intravascular insertion, according to group allocated prepared mixture of drugs (14-ml) was slowly injected in epidural space. The skin cephalad to the injection was palpated to ensure that the agent was not being injected subcutaneously. Care was taken to look for signs of acute toxicity during each caudal injection in all patients.

The bilateral pin-prick method was used to evaluate and check the sensory level while a modified Bromage scale (0 =no block, 1 = inability to raise extended leg, 2 = inability to flex knee and 3 = inability to flex ankle and foot) was used to measure the motor blockade effect at 5, 10, 15, 20, 25 and 30 minute intervals after the epidural administration of the drugs. After achieving complete sensory blockade in perianal area, patients were positioned in lithotomy.

Vital Recordings were made every 5 minutes until 30 minutes and at 10-minute intervals till end of surgery. Hypotension (defined as systolic arterial pressure falling more than 20% mm Hg) was treated with inj. mephenteramine 3–6 mg in bolus doses and HR<50 beats/min was treated with 0.3 mg of inj. atropine. Intravenous fluids were given as per the body weight and operative loss requirement, with no patient requiring blood transfusion.

Patients were transferred to the outpatient unit and patients should choose one of the terms: excellent, satisfactory or poor. Patients were discharged 4 hours after stabilization of vital signs for one hour, oriented, without nausea or vomiting, able to ingest liquids and walk. Patients were discharged after intravenous tramadol (100 mg) infusion at pain complaint. Time for injection and total sensory and motor block recovery ability to urinate and walk, Postoperative analgesia was induced with oral tramadol (100 mg) every 8 hours.

### *Statistical Analysis*

Data were analyzed by using SPSS (15.0) statistical software. The sample size determination was based on α risk of 0.05 and β risk of 0.10 which showed that 30 patients per study groups were needed. Data was presented as mean (±SD), or frequencies. Parametric data were analysedbyusing analysis of variance (ANOVA). Non parametric data were compared using the Chi-square test. A p value of <0.05 was considered significant.

## RESULTS

The demographic data were comparable with respect to age, BMI, sex, and ASA status in all groups. Moreover, there was no significant difference in the type of surgery and duration of surgery (Table 1). The age of group R, group RC and group RF ranged from 25-68 years, 21-68 years and 21-68 years respectively with mean (± SD) 47.1 (± 11.86) years, 46.75 (± 11.60) years and 46.77 (± 11.67) years respectively. Age distributions in all three groups were insignificant. Mean (± SD) of BMI in group R, group RC and group RF is 22.58 (± 1.51), 22.20 (± 1.42) and 22.69 (± 1.60) respectively. Further, in all three groups, the frequency of ASA grade I and ASA grade II have insignificant difference. The mean duration of surgery was around 23.06 (± 5.35) minutes in group R, 22.6 (± 5.98) minutes in-group RC and 23.63 (± 6.64) minutes in group RF. There is no significant difference between all three groups (Table 1).

**Table 1** Demographic profile

| | Group R n=30 | Group RC n=30 | Group RF n=30 | P value |
|---|---|---|---|---|
| | Mean ± SD | Mean ± SD | Mean ± SD | |
| Age (years) | 47.1 ± 11.86 | 46.75 ± 11.60 | 46.77 ± 11.67 | 0.991* |
| BMI | 22.58 ± 1.51 | 22.20 ± 1.42 | 22.69 ± 1.60 | 0.428 * |
| Sex | | | | |
| Male | 26 | 27 | 25 | 0.89# |
| Female | 4 | 3 | 5 | |
| ASA grade | | | | |
| ASA1 | 17 | 12 | 19 | 0.175# |
| ASA2 | 13 | 18 | 11 | |
| Type of surgery | | | | |
| Hemorrhoidectomy | 14 | 18 | 12 | |
| Fistulectomy | 8 | 7 | 6 | 0.340 # |
| Sphincterotomy | 8 | 5 | 12 | |
| Duration of surgery (mins) | 23.06 ± 5.35 | 22.6 ± 5.98 | 23.63 ± 6.64 | 0.801* |

Data are represented as mean, ±SD, n (%) and ratio. SD=Standard deviation,n
*= ANOVA, #=chai squire

Various block characteristics like onset of sensory blockade and motor blockade, highest dermatome level of sensory analgesia and maximum degree of motor blockade achieved were similar in all the three groups intraoperatively (Table 2). Mean time of onset of sensory blockade with SD was 17.00 (± 6.20) min in group R, 17.66 (± 6.43) min in group RC and 17.83 (± 6.35) min in group RF. Further, mean time of onset of motor blockade with SD was 22.83 (3.13) min in group R, 22.66 (± 2.85) min in group RC and 23.16 (± 2.78) min in group RF. Comparing the mean of epidural block characteristic in all three groups shows similar (p> 0.05) characteristics i.e did not differ statistically (Table 2).

**Table 2** Intraoperative caudal epidural block characteristics

| | Group R n=30 | Group RC n=30 | Group RF n=30 | P Value |
|---|---|---|---|---|
| | Mean ± SD | Mean ± SD | Mean ± SD | |
| Onset of sensory blockade (mins) | 17.00± 6.20 | 17.66± 6.43 | 17.83± 6.35 | 0.401* |
| Onset of motor blockade (mins) | 22.83± 3.13 | 22.66± 2.85 | 23.16± 2.78 | 0.797* |
| Highest dermatome level of sensory analgesia | | | | |
| T12 | 3 (10%) | 1 (3.3%) | 3 (10%) | |
| L1 | 22 (73.4%) | 28 (93.4%) | 20 (66.7%) | 0.356# |
| L2 | 5 (16.6%) | 1 (3.3%) | 7 (23.3%) | |
| Maximum degree of motor blockade achieved | | | | |
| 1 | 8 (26.6%) | 4 (13.4%) | 9 (30%) | 0.271# |
| 2 | 22 (73.4%) | 26 (86.6%) | 21 (70%) | |

Data are represented as mean, ±SD, n (%) and ratio. SD=Standard deviation, *= ANOVA, #=chai squire

Hemodynamic parameters were stable throughout the surgery in groups R, group RC and group RF as shown in Fig. 1, Fig. 2 and Fig. 3.

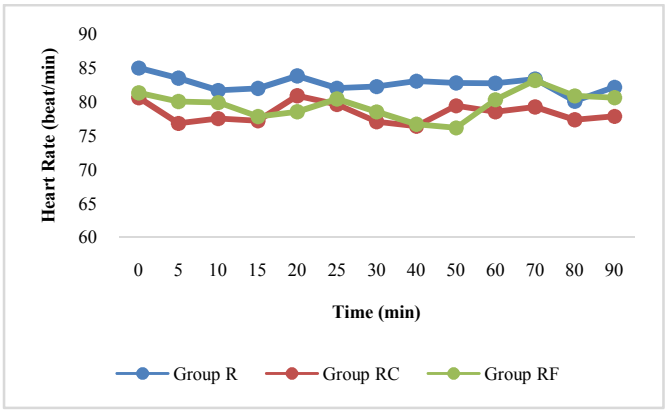


**Fig 1** Heart rate intraoperative

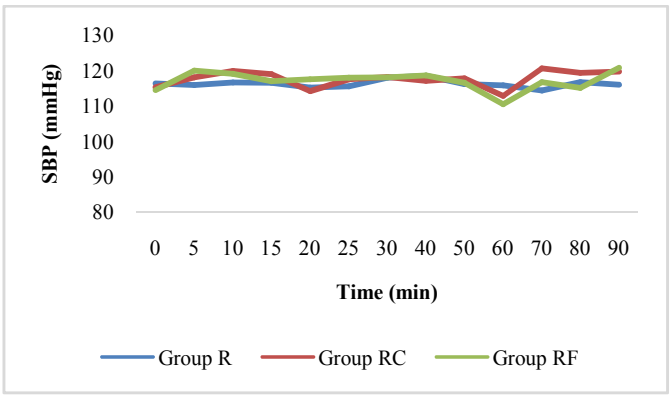


**Fig 2** SBP intraoperative

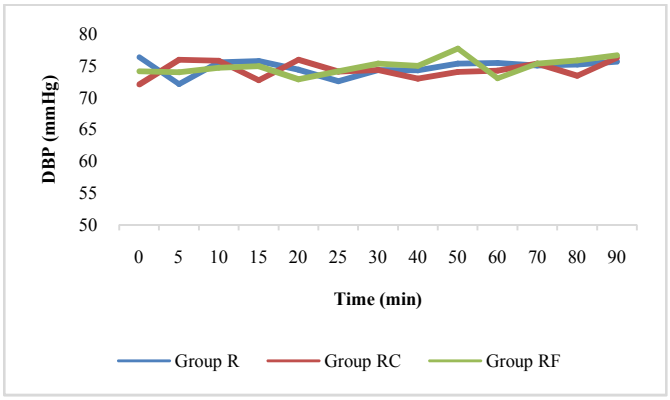


**Fig 3** DBP intraoperative

On comparing the mean time of first rescue analgesia in post-operative period with SD, 235.5 (± 90.75) min in group R, 279.5 (± 89.49) min in group RC and 292.33 (± 94.51) min in group RF, shows statistical significance difference (p=0.047) in between inter-group and between group R and group RF. While on comparing between group RF and group RC, no significant difference was seen. The other parameters like time of walking without support, time of first voiding and duration of hospital say, no significant statistical difference(p>0.05) (Table 3).

**Table 3** Postoperative caudal epidural block characteristics

| | Group R n=30 Mean±SD | Group RC n=30 Mean±SD | Group RF n=30 Mean ±SD | P Value | Tukey HSD (p-Value) | | |
|---|---|---|---|---|---|---|---|
| | | | | | R vs RC | RC vs RF | R Vs RF |
| Time of first rescue analgesia (mins) | 235.5±90.75 | 279.5±89.49 | 292.33±94.51 | 0.046* | 0.156 | 0.833 | 0.047* |
| time of walking without support (mins) | 114.11±18.71 | 114.33±19.72 | 112.66±17.30 | 0.929 | 0.899 | 0.895 | 0.899 |
| Time of first voiding (mins) | 262±81.24 | 301.83±86.42 | 303.1690.59 | 0.115 | 0.178 | 0.899 | 0.159 |
| Duration of hospital stay (Hrs) | 299.83±82.45 | 325.50±84.94 | 321.83±84.70 | 0.444 | 0.468 | 0.898 | 0.565 |

Data presented as mean ± SD, *=Significant (p <0.05)

## DISCUSSION

In our study we observed that there were no significant difference in haemodynamic parameters in between the groups, intra-operatively and post-operatively. In our study all groups are haemodynamically stable. Our results are supported by similar findings of previous studies by Bajwa*et al*. (2010a) and Khatavkar*et al*. (2016), who found that the MAP and mean HR were comparable in all the three groups (group RC, group RF and group RCF) during the entire procedure as well as post-op, which was a non-significant value on statistical comparison (P>0.05). Similarly in this study the pulse oximetry trends did not show any significant variation in patients of all the three groups. Shukla *et al*. (2011) found that the MAP and HR, at induction, intra-operatively and post-operatively were similar in ropivacaine-clonidine and ropivacaine-fentanyl group. MAP decreased in both groups by 10-15% during anaesthesia and increased by 5-15% during recovery but the changes were not significant.

Our results showed that the oxygen saturation was comparable in all three groups with no fall in the level of $SpO_2$. Similarly, various previous studies reported that the oxygen saturation was not affected by drug adjuncts (low dose) such as clonidine and fentanyl with ropivacaine.

In this study, we observed that the block characteristics such as onset of sensory and motor blockade, highest dermatome for sensory blockade, and maximum degree of motor blockade were similar in three groups. Bajwa *et al*. (2010b) reported that the onset of anaesthesia was shorter in group RC as compared to group R. However, once sensory level was established at T6-T7 level, there was no noticeable difference in sensory anaesthesia in either of the groups throughout the surgical procedure. The establishment of complete motor blockade was much earlier in the RC group which was again statistically significant. Agarwal *et al*. (2016) found that onset of sensory block to T10 was comparable between clonidine and fentanyl group but time to achieve maximum sensory level at T6-7 and maximum motor block was faster when fentanyl was used as compared to clonidine. Duration of sensory analgesia was enhanced with epidural clonidine.

Baglur *et al*. (2015) also reported that onset of anaesthesia was faster in fentanyl and clonidine group when compared to ropivacaine alone, with statistically significant variation in between fentanyl and clonidine group.

Furthermore, in our study, addition of clonidine or fentanyl was effective in increasing duration of analgesia as compared to ropivacaine group. Moreover, time for first rescue analgesia was significantly different between fentanyl with ropivacaine (group RF) and ropivacaine alone (group R) but it was comparable between group RC and group RF. Bajwa *et al*. (2010a) reported that the increase in duration of analgesia on addition of clonidine (2µg/kg) to 0.25% ropivacaine in paediatric populations in caudal block after the induction of general anaesthesia. Agarwal *et al*. (2016) also found that clodinine was more effective than epidural adjunct to 0.75% rupivacaine for prolonging the duration of analgesia with fewer manageable side-effects.Constant *et al*. (1998), Bajwa *et al*. (2010b) and Shukla *et al*. (2011) have also found similar finding in duration of analgesia as of our study that is duration of analgesia was comparable between clonidine group and fentanyl group. The mean duration of analgesia was longer in clonidine than in fentanyl, but the difference was not statistically significant ($P > 0.05$). Whereas in our study fentanyl group had longer duration of analgesia as compared to clonidine group. This difference in observation can be attribute to those of adjunct use. Constant *et al*. (1998) had used clonidine in dose of 1.5 µg/kg and fentanyl 1 µg/kg while Shukla *et al*. (2011) had used clodinine in dose of 2 µg/kg and fentanyl 1 µg/kg.

In this study, we observed that the time of first voiding was more in fentanyl or clonidine group as compared to ropivacaine, but it was not significantly different. This may occur due to low dose of adjunct used in caudal block in our study. Urinary retention is one of the complications following ano-rectal surgery. The urinary retention does not depend on the method of anaesthesia (Petros *et al*., 1990; Pertek *et al*., 1995). It was found that opioids used in any form increases the probability of urinary retention especially when used in spinal or epidural way. While comparing the other post-operative parameters Time of walk without support, and duration of hospital stay was comparable in all three groups. Our study has shown that using clonidine or fentanyl in dose of 25 µg would not cause recovery delay.

In this study we did not found any complication such as bradycardia/tachycardia, hypotension, desaturation and apnoea during intra-operative and post-operative period, we also didn't reported any side effect such as nausea, vomiting, drowsiness and itchingin any of three groups. Various previous study Bajwa *et al*. (2010a) and Shukla *et al*. (2011) have shown few incidences of mild to moderate sedation in both groups, but it was comparable. Our study finding can be explained by lower adjunct dose as compared to previous study.

## CONCLUSION

This present study have shown that the single shot caudal epidural block with ropivacaine with adjunct (clonidine/fentanyl) is an effective regional anaesthesia for adult out –patient ano-rectal surgery. It provides improved post-operative recovery and prolonged analgesia. Moreover, the ropivacaine with clonidine was more effective for postoperative analgesia requirement as compared to ropivacaine with fentanyl.

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