

Comparative Study of Epidural Ropivacaine versus Ropivacaine Clonidine

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Original Research Article

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Article History

Received: 01.06.2018

Accepted: 05.06.2018

Published: 30.06.2018

DOI:

10.21276/sjams.2018.6.6.43



Abstract: This is a prospective randomised study conducted at yashoda hospital with the aims to determine the qualitative and quantitative aspects of epidural block, hemodynamic effects, and postoperative pain relief of ropivacaine 0.75% versus ropivacaine 0.75% with 75mcg clonidine in lower limb orthopaedic surgeries. This study was conducted in 60 patients belonging to ASA grade I and II, scheduled to undergo lower limb orthopaedic surgery (total knee replacement). After random allocation into two different groups R and RC, 30 patients in each group, patients in group RC received 20ml of 0.75% ropivacaine and 75 µg of clonidine. Group R patients were administered 20ml solution of 0.75% ropivacaine. Surgical procedures were initiated after the establishment of adequate surgical anaesthetic effect with minimum level up to T10 dermatome. The onset, time to reach peak sensory and motor level, duration of Analgesia and Motor block, hemodynamic changes, and side effects were recorded. Statistical analysis was done using T-test and ANOVA. P value of less than 0.05 was considered to be significant. The onset of sensory blockade was earlier in Group RC, which was statistically significant ($P < 0.05$). Once sensory level was established at T8 - T10 level, there was no noticeable difference in sensory anaesthesia in two groups throughout the surgical procedure. The onset of motor blockade was earlier in Group RC but statistically not significant ($P > 0.05$), but the establishment of complete motor blockade was earlier in the RC group which was statistically significant, when compared to Group R ($P < 0.05$). The hypotension was treated with incremental doses of mephenteramine 3 – 6 mg bolus doses. The requirement was more in Group RC but statistically not significant.

Keywords: epidural ropivacaine, epidural ropivacaine clonidine in intra and post-operative analgesia.

INTRODUCTION

Regional anesthesia has been a popular anesthesia technique for suitable patients undergoing lower limb surgeries. The techniques include spinal, epidural or combined spinal and epidural. Benefits include decreased post-anesthesia care unit use, nausea and postoperative pain, therefore the requirement of analgesics is reduced [1].

Spinal anaesthesia is associated with adverse effects like sudden hypotension, bradycardia, post dural puncture headache, delayed mobilization. In combined spinal epidural, the right placement of the epidural catheter cannot be tested until the effect of spinal anaesthesia wears off. A sole epidural technique avoids the complications associated with dural puncture and sudden sympatholysis. Continuous epidural has a better control over sensory level. Epidural anaesthesia is preferred in high risk patients who may not tolerate the sudden sympathectomy associated with spinal anaesthesia.

Epidural anaesthesia and analgesia is widely used in patients as it can provide relief from pain for a longer duration. The facility of further top-ups and continuous infusion of the analgesic drugs through epidural catheter can provide a smooth and uneventful recovery. Epidural can also provide blockade in selected segments, useful in high-risk individuals.

Local anaesthetics have been the standard in any epidural regime. Bupivacaine has been increasingly replaced by ropivacaine for its similar analgesic properties, less motor blockade and decreased propensity of cardio toxicity. Ropivacaine, is a long-acting amide local anaesthetic related structurally to bupivacaine [2,3].

A slightly larger dose of Ropivacaine is required to achieve the analgesic and anaesthetic effects as compared to bupivacaine. The addition of adjuvant can decrease the dose of ropivacaine required

thereby eliminating the side effects associated with larger doses of ropivacaine[4].

Adjuvant drugs are pharmacological agents possessing little pharmacological effect by themselves, but enhance or potentiate the action of other drugs when given at the same time. Knowledge and use of adjuvant drug therapy has rendered neuraxial analgesia more effective in the management of both acute and chronic pain conditions.

Commonly used adjuvants in epidural anaesthesia are opioids and alpha-2 adrenergic agonists. Opioids given by epidural route to relieve post-operative pain can also be associated with mental confusion, somnolence, nausea and vomiting, itching and respiratory depression when given in high doses [5-8].

Clonidine an alpha-2 adrenergic agonist produces analgesia via non-opioid mechanism. Clonidine augments the action of local anesthetics in regional blockades by interrupting the neural transmission of painful stimuli in A δ and C fibres. In addition, augments the blockade of local anesthetic agents by increasing the conductance of K⁺ ions in nerve fibres. It also exerts a vasoconstricting effect on smooth muscles, which results in a decreased absorption of the local anesthetic drug and eventually prolongs the duration of analgesia [9]. At low doses, epidural clonidine improves the quality of anaesthesia, reduces the dose requirement of the anaesthetic agent and provides a more stable cardiovascular course during anaesthesia[10]. At higher doses, it may further reduce the dose of local anaesthetic and prolong the analgesic duration, but can exert its toxic effects resulting in profound hypotension, bradycardia and deep sedation[11].

The patient can be mobilized early post-operatively due less motor blockade of ropivacaine, which can prevent complications like deep vein thrombosis, pressure sores. The use of clonidine gives more hemodynamic stability post-operatively[12].

OBJECTIVES OF THE STUDY

- To compare onset of sensory block.
- To compare onset of motor block.
- To compare the duration of analgesia and motor blockade.
- To compare vitals like Heart rate and Mean blood pressure.
- To assess the Requirement of sedation to allay anxiety.
- To assess requirement of Mephentermine to maintain hemodynamic stability.
- To compare the side effects in both the groups.

MATERIALS AND METHODS

The present study “Randomized comparative study of Epidural Ropivacaine versus Ropivacaine–Clonidine in intra and post-operative analgesia for lower limb orthopaedic surgery” was carried out in YASHODA HOSPITAL in the department of anaesthesiology during the period from October 2012 to march 2014.

The study included total 60 patients, 30 in each group belonging to ASA grade I and II of either sex with age between 45 – 75 years posted for knee replacement surgeries.

Sample size was decided in consultation with a statistician and based on previous studies carried out by J M Engel *et al.* [13], Dobrydnjov I [14], Sukhminder Jit Singh Bajwa *et al.* [15]. A simple random technique was used to select sample population.

Inclusion criteria

- ASA I-II adult subjects.
- Age 40-75 years, of either sex.
- Weighing between 60 to 85 kgs.
- Height > 150 cms.
- Plan for lower limb surgery, under epidural anaesthesia.
- Willingness to be contacted postoperatively.
- Written informed consent.

Exclusion criteria

- Age > 75.
- ASA III, IV or V adults.
- Height <150cm
- Weight <60 kgs or >100kgs
- Inability to understand protocol due to language barrier.
- Patients who are physically dependent on opioids
- Patients with failed blocks or inadequate or incomplete blocks
- Patients on beta blockers
- Hypersensitivity to amide local anesthetics
- Uncontrolled anxiety
- Schizophrenia or bipolar disorder
- Peripheral neuropathy
- Significant cardiovascular disease
- BMI > 35.
- Uncontrolled diabetes
- Renal Impairment (Creatinine > 2.0 mg/dl)
- Ongoing drug abuse or alcohol abuse
- Contraindications for epidural anaesthesia like
- Raised intracranial tension
- Coagulation defects
- Uncooperative patients
- Severe hemorrhage
- Local infection /inflammation

TECHNIQUE

The study groups received Epidural Anaesthesia

Group RC received 20ml of 0.75% ropivacaine and 75 µg of clonidine. (Total volume 20.5 ml)

Group R received 20ml solution of 0.75% ropivacaine and 0.5 ml normal saline. (Total volume 20.5 ml)

The total volume injected was 20.5 ml in all groups. The time of injection of drug was noted. The following parameters were observed:-

Sensory blockade

Onset of sensory block was assessed by bilateral pin prick sensation method. It was subjectively studied by cold swab. The patients were tested every minute at one fixed dermatome level L4 level (knee). Initial period of onset of sensory blockade and the highest dermatomal level was noted.

Motor blockade

It was assessed by straight leg rising while lying supine and was graded according to modified Bromage scale.

Analgesia

Visual Analogue Scale (VAS) was used to assess the intensity of pain and pain relief. Duration of analgesia - It is the time interval between the start of analgesia, till patient complaints of pain (that is when VAS score is >40mm) when rescue analgesia was given.

Central effects

Mainly sedation was studied as the central effects. The sedation was graded according to Modified Ramsey Sedation Scale.

Side effects

Intra-operative side effects like sedation, nausea, vomiting, dry mouth, shivering, bradycardia (heart rate less than 50/min), and hypotension requiring active treatment and were also noted.

Hypotension was defined as more than 20 % fall in blood pressure from baseline systolic blood pressure value. Hypotension was treated with small incremental doses of IV Inj. Mephentermine 3-6mg and crystalloids.

Bradycardia was defined as heart rate less than 50 /min and was treated with IV Atropine 0.3mg in incremental doses.

All the parameters were recorded as per the proforma and subjected to statistical analysis.

STATISTICAL METHODS

The observations recorded in each group were compared using statistical analysis. Descriptive statistical analysis has been carried out in the present study. Institutional Ethical Committee approval was obtained.

OBSERVATIONS AND RESULTS

Our study was conducted on 60 patients who were randomly allocated into group R and group RC consisting of 30 patients each. Minimum age recorded in our study was 45 years and maximum age was 74 years. The mean age of patient in group R was 60.5333 ± 7.5919 years while the mean age of patient in group RC was 61.6667 ± 8.3473 years. The P value was 0.584 which signifies that the two groups were comparable with regards to Age.

Mean weight of patients in group R was 70.0000 ± 5.5647 kgs and mean weight of patients in group RC was 72.2667 ± 5.2715 . The P value was 0.111 which is not significant showing that the groups are comparable with regards to Weight.

Mean height of patients in group R was 161.167 ± 5.279 cms while mean height of patients in group RC was 162.80 ± 5.255 cms. The P value was 0.235 which was again insignificant and group I and II are comparable with regards to height.

Thus the patients in our study group were comparable with respect to Age, Weight and Height eliminating bias (if any) which can occur due to these factors.

In our study Sex distribution in both groups was equivalent with group R having 43.3% males & 56.6% females and group RC having 50 % males & 50% females. The P value was 0.612 Thus both groups were comparable for sex distribution.

In our study ASA GRADE distribution in both groups was equivalent with group R having 46.6% belonging to Grade I & 53.3% belonging to Grade II and group RC having 43.3% belong to Grade I & 56.6% belong to Grade II. Thus both groups were comparable with respect to ASA Grade distribution.

In our study, the minimum time of onset of sensory block was 3 minutes and maximum time was 8 minutes. Mean time of sensory onset with Group R was 6.5 ± 1.167 , with Group RC was 5.4 ± 1.163 . ($p = 0.001$).

Minimum time of onset of motor blockade was 6 minutes and maximum time was 13 minutes. Mean time of Motor onset with Group R was 9.2 ± 1.562 minutes, with Group RC was 8.4 ± 1.655 minutes. ($p=0.083$)

Minimum time to reach the T10 sensory level was 5 minutes and maximum time was 14 min. Mean time required to reach the maximum level of sensory

block in Group R was 9.967 ± 1.217 minutes, in Group RC was 9.30 ± 2.292 minutes. (p= 0.165)

Table-4: Comparison of Onset parameters in two groups

Range	Group R			Group RC			P Value
	Min	Max	Mean \pm SD	Min	Max	Mean \pm SD	
Onset of Sensory (In Mins)	4	8	0.001	3	7	5.4 ± 1.163	0.001
Onset of Motor (In Mins)	7	13	9.2 ± 1.562	6	12	8.4 ± 1.655	0.083
T10 Sensory level (In Mins)	8	13	9.967 ± 1.217	5	14	9.30 ± 2.292	0.165
Time to achieve Bromage score 2 (In Mins)	10	25	16.467 ± 4.117	8	16	12.667 ± 2.106	0.000

T-test is applied. P value is significant if <0.05 .

Minimum time to reach Bromage score 2 was 8 minutes and maximum time was 25 minutes. Mean time required to reach bromage score 2 in Group R was 16.467 ± 4.117 Minutes, in Group RC was 12.667 ± 2.106 Minutes. (p= 0.000)

The difference between Group R and Group RC was insignificant in terms of time for onset of motor blockade and time to achieve T10 sensory level but it was significant for onset of sensory blockade and time to reach the Bromage score 2 with group RC requiring more time as compared to group R .

Table-5: Comparison of maximum level of block achieved in two groups

Max level of sensory block	Group R		Group RC	
	N	%	N	%
T4	1	3.33%	2	6.66%
T6	6	20%	3	10%
T8	17	56.7%	13	43.3%
T10	6	20%	12	40%
Total	30	100%	30	100%

P value is 0.269

T- Test is applied. P value is significant if <0.05

In group R maximum level of T4 was achieved in 3.33 % subjects while 20% subjects had a maximum level of T6, maximum subjects achieved block upto T8 about 56.7 % and remaining 20 % of subjects achieved a maximum level of T10. In group RC the subjects achieving T4 level were 6.66 %, while those with T6 level were 10%, T8 level was

achieved in 43.3 % and the remaining 40 % had a maximum level of T10. (P value = 0.269).

Thus in our study there was no significant difference in both groups with respect to maximum level of block achieved.

Table-6: Comparison of Duration parameters in two groups:

Variable	Group R			Group RC			P Value
	Min	Max	Mean \pm SD	Min	Max	Mean \pm SD	
Duration of Surgery (In Min)	80	130	107 ± 13.3	95	125	111.1 ± 9.725	0.178
Duration of Analgesia (In Min)	140	305	236 ± 46.39	135	485	331.83 ± 83.71	0.000
Duration of Motor Block (In Min)	125	240	177.33 ± 30.27	125	445	267.17 ± 92.77	0.000

T- Test is applied. P value is significant if <0.05 .

The total duration of surgery was also comparable in both groups with mean duration in group R 107 ± 13.3 minutes and group RC 111.1 ± 9.725 Minutes. The P value was insignificant (0.178).

In our study, duration of Analgesia in Group R was 236 ± 46.39 minutes and in Group RC was 331.83 ± 83.71 minutes with p value of 0.000. Thus duration of Analgesia is statistically significant (p = 0.000) in Group RC as compared to Group R.

Duration of motor block in Group R was 177.33 ± 30.27 minutes and in Group RC was 267.17 ± 92.77 minutes, with p value of 0.000. Thus duration of

motor block was statistically significant (p= 0.000) in Group RC as compared to Group R with Clonidine having longer total motor blockade .

Table-7: Comparison of Heart rate between 2 groups

Sr No.	HEART RATE	Group R	Group RC	P value
		Mean ± SD	Mean ± SD	
1.	Baseline	84.50 ± 3.51	84.26 ± 3.16	0.941
2.	1 MIN	83.27 ± 3.31	85.10 ± 3.06	0.546
3.	3 MIN	81.00 ± 3.32	82.17 ± 2.62	0.681
4.	5MIN	80.53 ± 3.41	82.87 ± 2.66	0.423
5.	10MIN	79.40 ± 3.49	79.97 ± 3.32	0.861
6.	15MIN	78.47 ± 3.49	77.67 ± 3.39	0.807
7.	20 MIN	75.13 ± 3.64	71.50 ± 3.25	0.271
8.	30 MIN	73.43 ± 3.16	67.97 ± 2.70	0.054
9.	45 MIN	71.27 ± 3.10	65.33 ± 2.28	0.025
10.	60 MIN	70.43 ± 2.99	63.87 ± 2.29	0.012
11.	75 MIN	68.97 ± 2.88	62.87 ± 2.43	0.019
12.	90 MIN	67.70 ± 2.81	61.17 ± 2.53	0.012
13.	2 H	70.73 ± 3.34	66.70 ± 2.12	0.133

PARAMETERS	GROUP R	GROUP RC	P VALUE
	MEAN ± SD	MEAN ± SD	
HEART RATE AT 3 HOURS	70.57 ± 12.33	65.38 ± 9.85	0.084
HEART RATE AT 4 HOURS	70.50 ± 9.30	68.82 ± 11.62	0.535

ANOVA is applied. P value <0.05 is significant
T- Test is applied. P value is significant if <0.05.

So in our study the baseline Heart rate was comparable in both groups with no significant difference at 30mins. Then there was a significant decrease in Heart rate in Ropivacaine Clonidine group

as compared to Plain Ropivacaine group. However, it was maintained within the physiological range. After 2hrs there was no significant difference in 2 groups.

Table-8: Comparison of Mean arterial Blood Pressure between 2 groups

Sr No.	MEAN ARTERIAL PRESSURE	Group R	Group RC	P value
		Mean ± SD	Mean ± SD	
1.	Baseline	94.97 ± 3.01	97.50 ± 3.42	0.410
2.	1 MIN	90.50 ± 3.54	94.07 ± 3.62	0.297
3.	3 MIN	84.43 ± 3.98	87.93 ± 3.36	0.319
4.	5MIN	81.50 ± 4.01	83.40 ± 2.59	0.554
5.	10MIN	80.17 ± 3.99	77.37 ± 2.67	0.387
6.	15MIN	77.10 ± 3.98	75.13 ± 2.34	0.527
7.	20 MIN	80.00 ± 3.63	74.37 ± 2.34	0.056
8.	30 MIN	78.73 ± 3.30	74.47 ± 2.58	0.134
9.	45 MIN	78.87 ± 3.91	77.27 ± 3.33	0.643
10.	60 MIN	79.10 ± 3.89	78.73 ± 2.86	0.910
11.	75 MIN	81.07 ± 3.98	77.23 ± 3.51	0.284
12.	90 MIN	84.83 ± 4.06	75.23 ± 3.32	0.008
13.	2 H	81.10 ± 3.88	79.20 ± 4.22	0.622

ANOVA is applied. P value <0.05 is significant

PARAMETERS	GROUP R	GROUP RC	P VALUE
MEAN ARTERIAL PRESSURE AT 3 HOURS	90.75 ± 12.63	81.24 ± 12.58	0.006
MEAN ARTERIAL PRESSURE AT 4 HOURS	92.75 ± 10.42	82.55 ± 12.47	0.004

T- Test is applied. P value is significant if <0.05.

So in our study the baseline Mean blood pressure was comparable in both groups with no significant difference till 75 mins. Then there was a significant fall in blood pressure in Ropivacaine

Clonidine group as compared to plain Ropivacaine group. However, it was maintained within the physiological range.

Table-9: Comparison of incidence of side effects between 2 groups

Parameter	Group R (n=30)	Group RC(n=30)	P Value
Hypotension	16(53.33%)	17(56.66 %)	0.799
Bradycardia	2(6.66%)	2(6.66%)	1.000
Nausea/Vomiting	3(10%)	5(16.67%)	0.456
Shivering	11(36.67%)	5(16.67%)	0.082
Dry mouth	3(10%)	10(33.33%)	0.028

So from our study we concluded that incidence dry mouth is more with Ropivacaine Clonidine as compared to plain Ropivacaine group.

There was no significant difference in incidence of hypotension, bradycardia, nausea and vomiting, and shivering in both groups.

PARAMETERS	GROUP R	GROUP RC	P VALUE
	MEAN ± SD	MEAN ± SD	
REQUIREMENT OF MEPHENTERMINE (mg)	11.143 ± 5.573	11.471 ± 8.232	0.900
REQUIREMENT OF MIDAZOLAM (mg)	1.600 ± 0.498	1.400 ± 0.498	0.125
REQUIREMENT OF FENTANYL (mcg)	4.667 ± 14.559	0.000	0.084
REQUIREMENT OF PETHIDINE (mg)	26.111 ± 6.972	26.000 ± 5.477	0.976

In our study groups, the requirement of Mephentermine in Group R was 11.143 ± 5.573 mg and Group RC was 11.471 ± 8.232 mg. The p value is insignificant (0.900). There is no significant difference in mephentermine requirement in both the groups.

The requirement of Midazolam in Group R was 1.600 ± 0.498 mg and Group RC was 1.400 ± 0.498 mg to maintain Ramsay sedation scale 2 – 3. The p value is insignificant. (0.125). There is no significant difference in Midazolam requirement in both the groups.

The requirement of Fentanyl in Group R was 4.667 ± 14.559 mcg and Group RC was 0.000 mcg to maintain Ramsay sedation scale 2 – 3. The p value is insignificant. (0.084). There is no significant difference in fentanyl requirement in both the groups.

The requirement of Pethidine in Group R was 26.111 ± 6.972 mg and Group RC was 26.000 ± 5.477 mg to reduce shivering peri-operatively. The p value is insignificant (0.976). There is no significant difference in Pethidine requirement in both the groups.

DISCUSSION

Demographic data

The age, weight, height, sex, ASA grade and duration of surgery of the patients in both groups were comparable which shows that the patients of equal age, weight, height, sex and ASA grade were enrolled in the

study. The patients in both groups in the present study compare favorably with those of other studies such as by Sukhminder Jit Singh Bajwa *et al.*[15], De Kock *et al.*[16].

The demographic data such as age, sex, height, weight, ASA grade and duration of surgery were comparable in both groups and seems to have no influence on outcome of the study.

SENSORY BLOCK

Onset of sensory block

In our study, the minimum time of onset of sensory block was 3 minutes and maximum time was 8 minutes. Mean time of sensory onset with Group R was 6.5 ± 1.167, with Group RC was 5.4 ± 1.163. (p = 0.001).

The mean onset of sensory blockade was comparable to the study by Sukhminder Jit Singh Bajwa *et al.* [15] in elective caesarean section.

Maximum level of sensory block

In group R maximum level of T4 was achieved in 3.33 % subjects while 20 % subjects had a maximum level of T6, maximum subjects achieved block up to T8 about 56.7 % and remaining 20 % of subjects achieved a maximum level of T10. In group RC the subjects achieving T4 level were 6.66 %, while those with T6 level were 10 %, T8 level was

achieved in 43.3 % and the remaining 40 % had a maximum level of T10. (P value = 0.269).

Minimum time to reach the T10 sensory level was 5 minutes and maximum time was 14 min. Mean time required to reach the maximum level of sensory block in Group R was 9.967 ± 1.217 minutes, in Group RC was 9.30 ± 2.292 minutes. (p= 0.165).

Similar, observations was made by Sukhminder Jit Singh Bajwa *et al.*[15] in elective caesarean section, Onset of anaesthesia was shorter in group RC as compared to group R. However, there was no difference in the level of anaesthesia achieved in both groups, 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.

Duration of Analgesia (in mins)

In our study, duration of Analgesia in Group R was 236 ± 46.39 minutes and in Group RC was 331.83 ± 83.71 minutes with p value of 0.000. Thus duration of Analgesia is statistically significant (p = 0.000) in Group RC as compared to Group R.

In previous study done by J M Engel [13] conducted a dose response relationship of clonidine in orthopaedic surgery, Observed the analgesia time with 150 mcg clonidine was 513.92 min (p=0.002), 460.148 min (p = 0.073) for 100 micrograms clonidine, 440.86 min (p = 0.057) for 75 micrograms clonidine compared with 347.114 min for saline.

Landau Ruth *et al.* [4] studied women in early active labour. They observed that with clonidine, duration of analgesia was increased (132 ± 48 min [Group 1] and 154 ± 42 min [Group 3] versus 91 ± 44 min [Group 2];P < 0.05) .

Similarly, Sukhminder Jit Singh Bajwa *et al.* [15] observed that the duration of analgesia was longer in group with clonidine in patients undergoing elective caesarean section.

MOTOR BLOCK

Onset of Motor block

Minimum time of onset of motor blockade was 6 minutes and maximum time was 13 minutes. Mean time of Motor onset with Group R was 9.2 ± 1.562 minutes, with Group RC was 8.4 ± 1.655 minutes (p=0.083). There was no significant difference in both groups.

Minimum time to reach Bromage score 2 was 8 minutes and maximum time was 25 minutes. Mean time required to reach bromage score 2 in Group R was 16.467 ± 4.117 Minutes, in Group RC was 12.667 ± 2.106 Minutes. (p= 0.000).

Similarly, Sukhminder Jit Singh Bajwa *et al.*[15] observed Time to complete motor block (minutes) in Group R 21.70 ± 4.20 and in group RC 17.34 ± 4.48 in patients undergoing elective caesarean section.

In our study there was no significant difference with respect to onset of motor blockade in both groups but time to achieve Bromage score 2 was faster in group RC compared to group R as observed in other studies.

Duration of motor block

Duration of motor block in Group R was 177.33 ± 30.27 minutes and in Group RC was 267.17 ± 92.77 minutes, with p value of 0.000. Thus duration of motor block was statistically significant (p= 0.000) in Group RC as compared to Group R with Clonidine having longer total motor blockade.

De Kock *et al.* [16] observed the intensity of motor blockade assessed by the modified Bromage scale was significantly superior in patients who received clonidine 75mcg intrathecally for knee arthroscopy surgery.

Thus, in our study duration of motor blockade was significantly increased in Ropivacaine + Clonidine group and it was found to be more than that observed in previous studies.

Heart rate changes during surgery

In our study, the baseline Heart rate was comparable in both groups with no significant difference till 30mins. Then there was a significant decrease in Heart rate in Ropivacaine Clonidine group as compared to Plain Ropivacaine group, but was maintained within the physiological range. After 2hrs there was no significant difference in 2 groups.

Similar observation was made by Sukhminder Jit Singh Bajwa *et al.* [15] after 20 minutes of anesthetic dose, maternal heart rate kept on increasing in the R group but got stable in RC group and started decreasing thereafter which was statistically significant (P < 0.05) . The heart rate remained stable with hardly any fluctuation in either of the groups which is statistically nonsignificant

J M Engel *et al.* [13] carried out study of Dose response relationship of clonidine observed drop in heart rate in all groups. Similar, observation was made by Eisenach JC[29] in Epidural clonidine analgesia for intractable cancer pain.

Blood pressure changes during surgery

In our study the baseline Mean blood pressure was comparable in both groups with no significant difference till 75mins. Then there was a significant fall in blood pressure (maintained within physiological

range) in Ropivacaine Clonidine group as compared to plain Ropivacaine group.

Sukhminder Jit Singh Bajwa *et al.* [15] there were no significant difference of systolic BP in either of the groups ($P > 0.05$). The incidence of diastolic hypotension was more in clonidine group. This was explained on the basis of hypotensive action of clonidine causing a prolonged and significant diastolic hypotension in our patients.

Sukhminder Jit Singh Bajwa *et al.* [17] MAP and mean HR were comparable in all groups during the entire procedure as well as post-op, which was a non-significant value on statistical comparison ($P > 0.05$), when epidural clonidine and fentanyl was compared.

Side effects

In our study, the incidence of complications was as follow

There incidence of hypotension in group R and group RC was 53.33 % and 56.66 % respectively ,which was promptly treated with Inj. Mephentermine 3-6mg iv boluses.

The incidence of bradycardia in group R and group RC was similar 6.66 % in each group, which was treated with Inj. Atropine 0.6 mg IV bolus.

Nausea and vomiting was treated with inj. Ramoseteron 0.3mg IV. The incidence of nausea and vomiting in group R & RC was 10% and 16.67 % respectively. The difference was statistically insignificant.

Similarly incidence of shivering was statistically insignificant in both groups the percentage being 10 % and 33.33 % in group R & RC respectively

Incidence of dry mouth comparatively higher group RC 33.33 % than group R 10 % , which was statistically significant. ($p = 0.028$).

So from our study we concluded that incidence dry mouth is more with Ropivacaine Clonidine as compared to plain Ropivacaine group. There was no significant difference in incidence of hypotension, bradycardia, nausea and vomiting, and shivering in both groups.

Hypotension and Bradycardia were easily controlled with Inj Mephentermine and Inj Atropine.

Sukhminder Jit Singh Bajwa *et al.* [15] observed, there was no significant difference in both the groups with regard to nausea, vomiting, sedation, shivering, respiratory depression or headache ($P > 0.05$). Nine patients complained of dry mouth as

compared to none in the R group which was statistically significant.

De Kock M *et al.* [18] produced dose-dependent postoperative analgesia Epidural clonidine used as the sole analgesic agent during and after abdominal surgery without major side effects.

Sukhminder Jit Singh Bajwa *et al.*[17] observed 40% of the patients experienced nausea/vomiting when fentanyl was used in epidural as compared to 15% with use of clonidine. Sedation was observed in 30% of the patients with fentanyl use as compared to 10% in clonidine group.

In our study groups, the requirement of Mephentermine in Group R was 11.143 ± 5.573 mg and Group RC was 11.471 ± 8.232 mg. The p value is insignificant. (0.900). There is no significant difference in mephentermine requirement in both the groups.

Similarly Sukhminder Jit Singh Bajwa *et al.* [17] observed Mephenteramine requirement (mg) 10.78 with clonidine and 12.86 with fentanyl epidurally.

Sukhminder Jit Singh Bajwa *et al.* [15] observed, the requirement of mephenteramine was slightly higher in the clonidine group but it was not clinically significant. Hemodynamic side effects like hypotension and bradycardia neither had any major impact nor any sequel on the perioperative or postoperative course of mother.

In our study, the sedation scale was maintained between Ramsay sedation scales 2 – 3. The requirement of Midazolam in Group R was 1.600 ± 0.498 mg and Group RC was 1.400 ± 0.498 mg. The p value is insignificant. (0.125). There is no significant difference in Midazolam requirement in both the groups. Group R was also supplemented with fentanyl to allay anxiety, which was not required in group RC.

During our study, 3 patients had dural puncture during the epidural catheter placement. Catheter was placed in another space, these patients were managed medically, and they were monitored postoperatively. None of them had serious morbidity.

Two patients had patchy epidural block, general anaesthesia was given to these patients, and they were excluded from the study.

The results in our study showed that Clonidine $75\mu\text{g}$ can be used safely as an adjuvant to Epidural Ropivacaine to improve the quality of sensory blockade and duration of post-operative analgesia. Although there was incidence of hypotension in both groups but it was easily controlled with fluids and

Injection Mephentermine. However, incidence of dry mouth was comparatively more with clonidine use.

CONCLUSION

Epidural 0.75% of isobaric Ropivacaine provides efficient and safe anaesthesia for Lower limb Orthopaedic surgery. The addition of 75 µg Clonidine to isobaric Ropivacaine results in longer complete and effective analgesia with similar block properties, without any significant side effects. However, incidence of dry mouth was more with clonidine use.

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