ORIGINAL RESEARCH PAPER

Volume - 9 | Issue - 8 | August - 2020 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr

INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

A PROSPECTIVE RANDOMIZED STUDY TO COMPARE THE EFFICACY OF CLONIDINE & DEXMEDETOMIDINE AS ADJUVANTS TO ROPIVACAINE FOR POST OPERATIVE EPIDURAL ANALGESIA IN LOWER ABDOMINAL SURGERIES

Anaesthesiology

Dr. Sheema Bashir Senior Resident , Department of anaesthesiology and critical care , SKIMS Soura.

Dr. Umar Nisar Shah* Senior Resident, Department of anaesthesiology and critical care, SKIMS Soura. *Corresponding Author

Dr . Mehak Gul PG 3rd Year , Department of anaesthesiology and critical care , SKIMS Soura.

Dr. Zahid majid Senior Resident Department of anaesthesiology and critical care , SKIMS , Soura.

Dr.Showkat Gurcoo Professor , Department of anaesthesiology and critical care , SKIMS Soura.

ABSTRACT

Objectives : To compare the analgesic efficacy , quality , duration of postoperative analgesia, incidence of hemodynamic changes with ropivaciane in lower abdominal surgeries when used in combination with adjuvants (clonidine and dexmedetomidine) through epidural route. The study also includes the comparison of side effect profile of dexmedetomidine and clonidine and need for intravenous rescue analgesia in both groups.**Methods :** 80 patients were randomly allocated into two groups of 40 each GROUP 1 (RD), (n=40), received 10 ml ropivaciane 0.2% and dexmedtomidine 1µg/kg. GROUP 2 (RC), (n=40), received 10 ml ropivaciane 0.2% and clonidine 2µg/kg. After administering the drug, the following parameters were noted by the independent observer. It included pain score , Onset of analgesia , Peak level of analgesia , Duration of analgesia , Monitoring of vital parameters , Side effects such as nausea, vomiting, respiratory depression, motor blockade , deep sedation , shivering , hypotension and Requirement for IV rescue analgesics . Once the patient asked for additional epidural analgesia (VAS>4) for pain relief during the observation period, the study ended . **Results :** Our observations allow us to conclude that the epidural route provided adequate analgesia in lower abdominal surgeries in terms of VAS score and overall patient satisfaction and it avoided the need of iv analgesics in both the groups.Dexmedetomidine is a better neuraxial adjuant in comparision to clonidine for providing early onset and prolonged post-operative analgesia and stable cardiorespiratory parameters. Dexmedetomidine significantly prolonged the postoperative analgesia time without increasing the incidence of side effects like nausea, vomiting, pruritis or urinary retention. **Conclusion** : Dexmedetomidine is a better neuraxial adjuant in comparision to clonidine for providing early onset and prolonged post-operative analgesia and stable cardiorespiratory parameters.

KEYWORDS

INTRODUCTION

Pain has also been defined as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” by International Association for the Study of Pain1. Adequate analgesia is the hallmark and basic requirement of every anaesthetic technique. Surgery to anyone stands synonymous to pain. Primary fear of a person scheduled to undergoing surgery is pain2. Adequate post-operative pain relief leads to early mobilization, hastening of convalescence, decreased pulmonary complications, reduced incidence of deep vein thrombosis and reduction in hospital stay3. Postoperative pain continues to be a challenge and is often inadequately treated leading to patient anxiety ,stress and dissatisfaction [4,5,6]. Inadequately treated pain can lead to detrimental physiological effects and may also have psychological, economic and social adverse effects[4,5].

Relieving postoperative pain of abdominal surgeries has become an indispensable component in anaesthesiology7. Various methods have been tried for the management of post-operative pain in abdominal surgeries out of which epidural techniques are becoming most promising. Various methods of postoperative pain relief include general measures, which include preparatory information, reassurance and meditation, Non-Opioid analgesic drugs which include Acetaminophen (paracetamol) and NSAIDS, Systemic Opioids, Ketamine and Local and Regional Analgesia8. Epidural anesthesia is a safe and inexpensive technique with the advantage of providing surgical anesthesia and prolonged post-operative pain relief8. It is also an effective treatment of operative pain, blunts autonomic, somatic and endocrine responses.

Traditionally large volumes of local anesthetics are used, thereby increasing the possibilities of local anesthetic toxicity and deleterious hemodynamic consequences. In order to lower the toxicity due to large doses of local anesthetic adjuvants like Fentanyl, Clonidine, Dexmedetomidine, Magnesium etc are added to epidural anesthesia9,10. The newer amide local anesthetic ropivacaine, shares many physio chemical properties with bupivacaine but with less systemic toxicity and greater margin of safety than other local anesthetic agents of similar duration of action9,10. It has always been a matter of research to find out drugs or techniques to potentiate the quality of central neuraxial blocks, a variety of drugs, such as opioids, midazolam and alpha-2 agonists, were tried as an adjuvant with ropivacaine to prolong the duration of intraoperative and postoperative analgesia with variable results[11].

MATERIAL METHODS

After obtaining approval from ethical committee of the institute and informed consent, 80 patients of physical status ASA I and II of either sex, aged 18 to 65 years scheduled for lower abdominal surgeries (colorectal) were prospectively enrolled in this study. On visiting the patient preoperatively , preoperative evaluation was done and epidural catheter technique with its risks and benefits were explained to the patient. The inclusion criteria included Patients of American society of Anesthesiologists (ASA) class I and II , patients with age between 18 to 65 years , patients undergoing lower abdominal surgeries (colorectal surgeries). The exclusion criteria included patients with cardiac disease (heart blocks, significant bradyarrthymias, left ventricular failure), patients with hematological disease, patients with bleeding or coagulation abnormalities , patients with psychiatric diseases , patients with history of drug abuse and allergy to amide type of local anaesthetics , patients with hypertension, COPD (chronic obstructive pulmonary disease), spinal deformities and tubercular spine or any permanent neurological disorders .

Patients were given ranitidine 150 mg tablet a night before and on the morning before surgery. Patients were randomly allocated into two groups of 40 each GROUP1(GROUP RD), (n=40), received 10 ml ropivaciane 0.2% dexmedtomidine 1µg/kg.GROUP 2 (GROUP RC), (n=40), received 10 ml ropivaciane 0.2% and clonidine 2µg/kg. After administering the drug, the following parameters were noted by the independent observer : The pain score, by using VAS every 2 min for 30 min and then every 30 min until the need for next epidural top up , onset of analgesia (fall of VAS<4 after epidural drug), peak level of analgesia (achieving VAS score 0), duration of analgesia (starting from

epidural drug administration to once the patient asks for additional epidural analgesia with VAS>4), monitoring of vital parameters such as NIBP, pulse rate, respiratory rate every 10 min for a period of 30 mins and then every 30 mins till 1hr , Side effects such as nausea, vomiting, respiratory depression, motor blockade (Bromage scale>1), deep sedation (Ramsay sedation scale>3), shivering and hypotension and requirement for IV rescue analgesics (injection Diclofenac). Once the patient asked for additional epidural analgesia (VAS>4) for pain relief during the observation period, the study ended . Hypotension (which was defined as systolic arterial pressure falling more than 20% from the preoperative level) was treated by intravenous ephedrine 5 to 10 mg initial bolus and if heart rate decreased to <50 beats/min it was treated by 0.01mg/kg atropine. Postoperative maintenance IV fluids was given as per body weight. Nausea and vomiting was treated by 0.1 mg/kg of IV ondansetron.

In the operation theatre, an intravenous (IV) access with 18 gauge cannula was secured and all noninvasive monitoring devices noninvasive blood pressure (NIBP), electrocardiograph leads, pulse oximeter, esophageal temperature probe, end tidal carbon dioxide were attached and the baseline cardiorespiratory parameters were recorded. The monitoring devices used in the observation period were pulse, noninvasive blood pressure (NIBP), oximetry, VAS scale and continuous electrocardiogram. All cases of lower abdominal surgery were conducted under general anaesthesia. Before giving general anesthesia patient was prepared for epidural catheter placement and catheter technique was again explained and then 18 gauge epidural catheter was placed in the lumbar epidural space through a skin puncture in the inter-spinous space with 18 gauge Touhy's needle. The catheter was positioned up to 5cm beyond the tip of the needle into the epidural space to ensure optimal catheter position and to reduce the chances of catheter migration through paraspinous spaces and sub arachnoid space. The catheter was then anchored in place on the back of the patient using an adhesive tape and correct placement of catheter in epidural space with heme-negative and CSF-negative aspiration was confirmed and 3ml of injection xylocaine adrenaline was given as epidural test dose.

Patient was given general anesthesia using standard anesthetic technique. Induction was done using intravenous anesthetic agent propofol (2mg/kg) body weight + fentanyl (2mcg/kg) and atracurium (0.5mcg/kg). Anaesthesia was maintained with isoflurane (1MAC) + nitrous oxide 50% +oxygen 50%.Analgesia intraoperatively was given using ropivaciane 0.2% epidurally in all patients. After completing surgical procedure patients were extubated when fully awake following standard technique and shifted to post operative ward. Once the patient in the postoperative period was noted to have pain with VAS (visual analogue scale) of > 4, epidural top-up dose was given as per the group allocation randomly .

Most frequently used measure of motor block. In this scale the intensity of motor block is assessed by the patients ability to move their lower extremities. In our study motor block was assessed by modified bromage scale as follows:

Grade	
0	The patient is able to move hip, knee, ankle.
I	The patient is unable to move hip but is able to move knee and ankle
II	The patient is unable to move hip and the knee but is able to move the ankle
III	The patient is unable to move hip,knee and ankle.

Pain scores was measured on standard 10 point visual analogue scale (VAS 0=no pain, VAS 10=worst possible pain) every 2 mins for a period of 30 mins and then every 30 mins after admission to post operative ward until the need for next epidural top up . Ramsay sedation scale is frequently used to assess sedation in postoperative period.

Table showing Ramsay scale

SCORE	RESPONSE
1	Anxious or restless or both.
2	Cooperative ,oriented ,tranquil.
3	Responding to commonds.
4	Brisk response to stimulus.
5	Sluggish response to stimulus.
6	No response to stimulus.

STATISTICALANALYSIS:

The recorded data was compiled and entered in a spreadsheet (Microsoft Excel) and then exported to data editor of SPSS Version 20.0 (SPSS Inc., Chicago, Illinois, USA). Continuous variables were expresses as Mean ± SD and categorical variables were summarized as frequencies and percentages. Graphically the data was presented by bar and line diagrams. Student's independent t-test was employed for comparing continuous variables. Chi-square test or Fisher's exact test, whichever appropriate, was applied for comparing categorical variables. A P-value of less than 0.05 was considered statistically significant and value of < 0.001 was considered as statistically highly significant(p<0.001)All P-values were two tailed.

OBSERVATION AND RESULTS

The following data was collected and analyzed statistically : Age , gender , weight, height , ASA class, pain score using VAS, Onset of analgesia, Duration ,Peak of analgesia, rescue analgesics used , hemodynamic parameters after giving epidural drug , side effect profile after giving drug .

Table 1: Age distribution between two groups'

Age (years)	N	Mean	SD	Range	P-value
Group RD	40	51	5.57	35-60	0.144
Group RC	40	52.8	5.17	41-60	

Table showing that the demographic profile of the patients in both groups was comparable with respect to age which means that the patients did not differ significantly with respect to age.(p value >0.05)

Table 2: Gender distribution between two groups

Gender	Group RD		Group RC		P-value
	No.	%age	No.	%age	
Male	22	55	16	40	0.179
Female	18	45	24	60	
Total	40	100	40	100	

The patients in two groups did not differ significantly with respect to number of male and female patients in each group (p value>0.05) which means that the two groups were comparable with respect to gender.

Table 3: Comparison based on weight (kgs) between two groups

Weight (kgs)	N	Mean	SD	Range	P-value
Group RD	40	62.1	9.48	45-81	0.599
Group RC	40	63.4	7.84	47-82	

Table showing that the demographic profile of the patients in both groups was comparable with respect to weight which means that the patients did not differ significantly with respect to weight (p value >0.05).

Table 4: Showing mean height (cms) among two groups

Height (cms)	Mean	SD	Range	P-value
Group RD	166.8	5.84	156-180	0.795
Group RC	165.0	6.94	153-179	

Table 5: Distribution of study patients as per ASA in two groups

ASA	Group RD		Group RC		P-value
	No.	%age	No.	%age	
ASA I	33	82.5	35	87.5	0.531
ASA II	7	17.5	5	12.5	
Total	40	100	40	100	

The patients in two groups were comparable with respect to ASA status in both groups (p value < 0.05).

Table 6: Comparison based on onset of analgesia (Min) in two

groups

Onset of analgesia (Min)	N	Mean	SD	Range	P-value
Group RD	40	7.8	1.50	6-10	0.002*
Group RC	40	8.9	1.47	6-12	

Table showing comparison of onset of analgesia between two groups. In Group RD the onset of analgesia after drug administration is 7.8 ±1.50 min and in Group RC it is 8.9±1.47 min which is statistically significant difference with P value <0.05, showing that the onset of analgesia was faster in RD group compared to RC group .

Table7: Comparison based on peak level of analgesia (Min) between two groups

Peak level of analgesia (Min)	N	Mean	SD	Range	P-value
Group RD	40	11.9	1.46	10-16	<0.001*
Group RC	40	13.6	1.15	12-16	

*Statistically Significant Difference (P-value<0.05)

Table showing the comparison of peak level of analgesia achieved between two groups. In RD group peak level of analgesia was achieved in 11.9±1.46 min and in RC group it was achieved in13.6±1.15 min and the difference is statistically significant with P value of <0.05 showing that the peak level of analgesia was achieved more quickly in RD group compared to RC group

Table 8: Comparison based on duration of analgesia (Min) among two groups

Duration of analgesia (Min)	N	Mean	SD	Range	P-value
Group RD	40	387.8	22.93	360-420	<0.001*
Group RC	40	312.0	37.70	270-390	

*Statistically Significant Difference (P-value<0.05)

Table showing the comparison of duration of analgesia between the two groups. In Group RD duration of analgesia is 387.8±22.93 min and in Group RC duration of analgesia is 312.0± 37.70 min which is statistically significant difference with P value <0.05, showing that Group RD patients had prolonged analgesia compared to RC group.

Table showing that VAS score followed a decreasing trend from 0 to 14 min post injection in both the groups and at 4 min post injection the difference was statistically significant showing that in RD group the decrease in pain score was more compared to RC group and the same findings were present at 10 and 12 min post injection. From 16 min to 5 hrs patients in each group did not require epidural topups, the VAS scores were stable and patients were pain free

Table 9: Comparison based on VAS score among two groups at various time intervals

Time Interval	Group RD		Group RC		P-value
	Mean	SD	Mean	SD	
BL	6.45	0.75	6.48	0.85	0.889
2 M	5.83	0.75	5.95	0.85	0.486
4 M	5.03	0.73	5.45	0.88	0.021*
6 M	4.05	0.90	4.28	0.68	0.212
8 M	3.23	0.83	3.43	0.59	0.220
10 M	1.75	1.28	2.68	0.66	<0.001*
12 M	0.48	0.99	1.38	1.00	<0.001*
14 M	0.03	0.16	0.23	0.73	0.096
16 M	0.00	0.00	0.00	0.00	-
18 M	0.00	0.00	0.00	0.00	-
20 M	0.00	0.00	0.00	0.00	-
22 M	0.00	0.00	0.00	0.00	-
24 M	0.00	0.00	0.00	0.00	-
26 M	0.00	0.00	0.00	0.00	-
28 M	0.00	0.00	0.00	0.00	-
30 M	0.00	0.00	0.00	0.00	-
1 Hr	0.00	0.00	0.00	0.00	-
1.5 Hr	0.00	0.00	0.10	0.44	0.156
2 Hr	0.30	0.46	0.75	0.95	0.009*
2.5 Hr	0.55	0.75	0.98	0.97	0.032*
3 Hr	0.98	0.89	1.78	1.27	0.002*
3.5 Hr	2.25	0.90	3.13	0.88	<0.001*
4 Hr	2.53	0.93	3.80	0.56	<0.001*
4.5 Hr	3.10	0.44	4.53	1.22	<0.001*
5 Hr	3.53	0.51	5.17	1.29	<0.001*
5.5 Hr	3.78	0.42	4.86	1.10	<0.001*
6 Hr	4.65	1.25	5.25	1.39	0.230
6.5 Hr	5.59	1.48	6.50	0.58	0.235

but the VAS score started to increase from 2 hrs post injection but the drug was required only when VAS score was >4. The mean VAS score was higher in the RC group at each time interval and the difference was statistically significant at various time intervals and that RC group patients needed epidural topups earlier than RD group.

Table 10: Comparison based on heart rate (beats/min) in two groups

Time Interval	Group RD		Group RC		P-value
	Mean	SD	Mean	SD	
BL	103.8	11.08	104.4	6.36	0.767
10 M	97.5	7.34	95.8	5.93	0.258
20 M	89.6	5.37	87.9	5.95	0.178
30 M	83.9	5.94	78.2	5.24	<0.001*
60M	81.3	5.33	74.7	5.08	<0.001*

Table showing comparison of heart rates between two groups from administration of drug to 1hr after .There was no significant difference of HR in both the groups at the time of administration of drug. HR started to decrease in both the groups but the fall in RC group was more which became statistically significant at 30 mins post injection with P value <0.05 but none of the patients showed bradycardia (HR<60).

Table 11: Comparison based on mean arterial pressure (mmHg) in two groups

Time Interval	Group RD		Group RC		P-value
	Mean	SD	Mean	SD	
BL	99.4	7.05	99.8	5.33	0.817
10 M	95.3	4.99	93.5	4.92	0.091
20 M	91.6	4.02	90.1	3.86	0.093
30 M	86.5	3.21	83.4	4.04	0.003*
60M	85.3	3.01	80.5	4.18	<0.001*

Table showing comparison of mean arterial pressures (MAP) between two groups from administration of drug to 1hr after .There was no significant difference of HR in both the groups at the time of administration of drug. MAP started to decrease in both the groups but the fall in RC group was more which became statistically significant at 30 mins post injection with P value <0.05 but none of the patients showed hypotension (fall to >20% from baseline).

Table 12: Comparison based on respiratory rate in two groups

Time Interval	Group RD		Group RC		P-value
	Mean	SD	Mean	SD	
BL.	14.02	1.63	13.92	1.66	0.784
10 M	13.31	1.65	13.25	1.71	0.893
20 M	12.50	1.32	12.45	1.34	0.867
30 M	12.42	0.98	12.37	1.01	0.827
60M	11.95	0.74	11.87	0.79	0.664

Table showing comparison of respiratory rates between two groups from administration of drug to 1 hr after. There was a decrease in mean repiratory rates (RR) in both the groups after giving the drug and the difference between the groups was statistically not significant (P value >0.05) at different time intervals. None of the patients showed respiratory depression (RR<10).

Table 13: Showing various side effects in two groups

Side Effects	Group RD		Group RC		P-value
	No.	%age	No.	%age	
Sedation	8	20.0	6	15.0	0.556
Motor Block	0	0.0	0	0.0	1.000
Dry Mouth	2	5.0	3	7.5	0.646
Nausea	4	10.0	3	7.5	0.695
Vomiting	3	7.5	2	5.0	0.646
Headache	0	0.0	0	0.0	1.000
Pruritis	0	0.0	0	0.0	1.000
Urinary Retention	0	0.0	0	0.0	1.000

Table showing comparative incidence of various side effects in both the groups as observed in the post injection period .The incidence of dry mouth and sedation were similar in both the groups and also statistically non –significant. The incidence of other side effects such as nausea ,vomiting ,headache and shivering were comparable in both the groups and found to be statistically non significant (P value >0.05).None of the patients showed respiratory depression or motor block in either group.

DISCUSSION

The study involved random allocation of patients into two groups of 40 each

GROUP 1 (RD)…. received 10 ml 0f 0.2% ropivacaine +2mcg/kg dexmedetomidine.

GROUP 2 (RC) …. received 10 ml of 0.2% ropivacaine +1mcg/kg clonidine.

Both groups were homogenous with reference to age, sex weight, height, ASA

criteria. Mean age of patients was 51 years in RD group and 52.8 in RC group.

Percentage of males and females was 55 and 45 % respectively in RD group and 40 and 60 % respectively in RC group. Mean weight of patients in group RD was 62.1 kgs and in group RC was 63.4 kgs. Mean height of patients in group RD was 166.8 cms and in group RC was 165 cms .Percentage of ASA I and ASA II in group RD were 82.5 and 17.5 and in group RC 87.5 and 12.5 respectively. The difference was not statistically significant (p value>0.05).

In our study, VAS score was used to evaluate the efficacy of drugs given through epidural route. Since the study begins in the postoperative period, the residual effects of general anaesthesia drugs make the perception of mild pain (VAS<4) to differ among patients as most patients tolerate minimal pain in the postoperative period due to residual analgesia and hypnosis. We started the study with VAS>4 based on previous studies where postoperative epidural analgesia was given for VAS>412.

The onset of analgesia in group RD was 7.8±1.50 min and in group RC was 8.9±1.47min, the difference being statistically significant with a P value of 0.002.This signifies that the onset of analgesia was faster in ropivacaine +dexmedetomidine group compared to ropivacaine clonidine group.

Our observations correlate with MS SARVANA BABU et al. (2013) who also found earlier onset of ropivacaine + dexmedtomidine group compared to ropivacaine +clonidine group when they did a comparative study in thepost-operative spine surgeries where ropivacaine + dexmedtomidine and ropivacaine +clonidine was given in two different groups for postoperative epidural analgesia .

BHAWNA RASTOGI et al. (2015) also found early onset of ropivacaine+ dexmedtomidine group compared to ropivacaine only group when given epidurally in infra umblical surgeries. Our observations also correlate with SAFIYA SHEIKH et al (2016) who compared bupivacaine + dexmedtomidine and bupivacaine + clonidine andobserved that onset of analgesia was earlier in bupivacaine +dexmedtomidine group in patients undergoing lower limb orthopedic surgeries. Our observations are also in concordance with SHOBANA GUPTA et al. (2014) who found earlier onset of ropivacaine + dexmedtomidine group compared to ropivacaine + clonidine group in children undergoing caudal block.

Our observations are in discordance with ANTONIO MAURO VIEIRA et al. (2004) who found early onset of ropivacaine clonidine group compared to ropivacaine dexmedetomidine group when given epidurally for postoperative analgesia and sedation in patients undergoing subtotal cholecystectomy.The reason can be that the study group comprised only of 50 patients.

The duration of analgesia in RD group was 387.8±22.93 min compared to RC group where it was 312±37.70 min. The difference between two groups was statistically highly significant with a P value of <0.001.This shows that the duration of analgesia was more prolonged in ropivacaine + dexmedetomidine group compared to ropivacaine + clonidine group. Our study is in concordance with study done by MS SARVANA BABU et al. (2013) who found prolonged duration of ropivacaine +dexmedtomidine group compared with ropivacaine + clonidine group in post operative spine surgeries where drugs were given through epidural route .

SHOBANA GUPTA et al. (2014) also found similar results where post operative caudal analgesia was prolonged in ropivacaine + dexmedtomidine group compared to ropivacaine + clonidine group in children undergoing lower abdominal surgeries. Our observations were similar to study done by RAVINDRA S GIRI et al. (2013) who found prolonged post op epidural analgesia in ropivacaine + dexmedtomidine group compared to ropivacaine + normal saline group in patients undergoing lower abdominal and lower limb surgeries.

Our observations are also in concordance with SHILPI AGARWAL et al. (2015) who compared epidural dexmedtomidine added to bupivacaine withclonidine added to bupivacaine in infra umblical surgeries and found prolonged duration of bupivacaine +dexmedtomidine group when compared to bupivacaine +clonidine group . Our observations are in discordance with ANTONIO MAURO VIEIRA et al. (2004) who found prolonged duration of ropivacaine clonidine group compared to ropivacaine dexmedetomidine group when given epidurally for postoperative analgesia and sedation in patients undergoing subtotal cholecystectomy. The results of this study cannot be generalized as the study group comprised only of 50 patients.

In our study peak level of analgesia was achieved in 11.9 min ±1.46 min in RD group compared to RC group in which peak was achieved in 13.6±1.15 min. This was statistically significant with P value of <0.001 indicating that peak level of analgesia was achieved more quickly in ropivacaine + dexmedetomidine group compared to ropivacaine + clonidine group.

Similar results were found in study conducted by MS SARVANA BABU et al. (2013) who found early peak effect in RD group compared to RC group in spine surgeries when dexmedtomidine and clonidine added to ropivacaine were given through epidural route . Our observations were also in concordance to study done by SUKHMINDER JIT SINGH BAJWA et al. (2011) who also found earlier peak effect of ropivacine +dexmedtomidine group compared to ropivacaine+clonidine group when administered epidurally in patients undergoing lower limb orthopedic surgeries .

There was a significant change /decrease in VAS score from baseline VASscore post injection in both groups but the decrease was greater in RD group and at 4 min post injection this decrease became significant with P value 0.021. There was further decrease in VAS scoring after 4 min and decrease wasmore in RD group which became significant at 10 and 12 min post injectionwith P value <0.001 . At 4 to 5 hr post injection VAS scores showed increasing trend but the mean VAS scores were higher in RC group compared to RD group at different time intervals which was statistically significant with p value < 0.001. This shows that although epidural route provided good mode of analgesia in both the groups, dexmedetomidine improved the epidural efficacy13,14,15,16.

Our study correlates well with MS SARVANA BABU et al (2013) who also found similar results however they had statistically insignificant

difference at 5 to 6 hrs post injection . None of the patients in both the groups needed iv rescue analgesics (inj.diclofenac) throughout the study period. This shows that epidural routeprovided effective analgesia in both groups[17,18,19]. Epidural catheters were placed under direct vision in the epidural space during the perioperative period , still then epidural failure was seen in 5% of patients and these patients were not included in the study ,instead of them another 4 patients were taken. Although epidural route of analgesia increases the possibility of hemodynamic instability, the cardiorespiratory parameters remained stable throughout the study period, which reaffirms the established effects of α2 agonists in providing a hemodynamically stable post-operative analgesia[20]. A slight decrease in heart rate and mean arterial pressure was observed in both the groups and the decrease in RC group was statistically significant but none of the patients showed bradycardia or hypotension that is it never fell down to more than 20% of the baseline values[21]. Our study is in correlation to BRICHANT JF et al (1994) who also found incidence of hemodynamic instability more in ropivaciane +clonidine group compared to ropivaciane only group while studying the effect of admixture of clonidine to epidural ropivaciane for labour analgesia.

Our results are also in concordance with SUKHMINDER JIT SING BAJWA et al. (2011) who found stable cardiorespiratory parameters in ropivaciane +dexmedtomidine group compared to ropivaciane + clonidine group when given epidurally in patients undergoing vaginal hysterectomies.

MS SARVANA BABU et al (2013) found stable cardiorespiratory parameters in ropivaciane+dexmedtomidine group compared to ropivaciane+clonidin group when administered epidurally in patients undergoing spine surgeries.

This study is also in concordance to our study. Our observations are also in concordance with SAFIYA SHEIKH et al (2016) who found stable hemodynamic profile in bupivacaine + dexmedtomidine group compared to bupivacaine + clonidine group in patients undergoing lower limb orthopedic surgeries.

The sideeffect profiles of both these drugs are quite favourable as none of the patient in either group had profoundly deep sedation (sedation score>3) or respiratory depression21. Light sedation (sedation score ≤3) was found in both groups in almost equal proportions, but none of the patients had profound deep sedation (sedation score >3) in both groups. None of the patients in the study developed motor blockade, respiratory depression[16].

This can be attributed to lower concentrations of ropivacaine and the α2 agonistic properties of sedation with no respiratory depression. Our results are in concordance to EL-HENNAWAY AM et al. (2009) who in their study had no increase in incidence of side effects in bupivacaine + dexmedtomidine group compared to bupivacaine + clonidine group in children undergoing lower abdominal surgeries. Our results are also in concordance with SUKHMINDER JIT SINGH BAJWA et al (2010) who found no increase in incidence of side effects when ropivacaine +clonidine was given caudally in children compared to ropivaciane alone. Our study also correlates to BHAVNA RASTOGI et al. (2015) who found increased incidence of side effects in ropivaciane group compared to ropivaciane+dexmedtomidine group but sedation was more in ropivaci + dexmedtomidine group in patients undergoing infraumblical surgeries.
KHAGESWAR RAUT et al.(2015) found statistically significant sedation scores in ropivaciane +dexmedetomidine group compared to ropivaciane + clonidine group when given epidurally in lower limb orthopedic surgeries.

The incidence of other side effects was comparable in both groups.

The limitation of this study was that patients were followed for lesser time in post-operative period ,the study ended when the need for top up dose arose which was a maximum period of 6 to 7 hours, which is less compared to other studies. Another limitation of the study was that it was a single blinded study as a result of which some amount of bais could have been added .One more limitation of the study was that there was no smooth availability of clonidine and it was used of different brands so the quality control of the drug suffered.

CONCLUSION

Dexmedetomidine is a better neuraxial adjuant in comparision to clonidine for providing early onset and prolonged post-operative analgesia and stable cardiorespiratory parameters.

Dexmedetomidine significantly prolonged the postoperative analgesia time without increasing the incidence of side effects like nausea, vomiting, pruritis or urinary retention. All the patients in our study remained hemodynamically stable throughout the postoperative period and none of the patients in our study developed respiratory depression (SpO2 < 95%). The requirement of rescue analgesic doses in postoperative period was significantly less in both groups.

REFERENCES:

1. Mersky H, Albey Fessard D.G, Bonica JJ. pain terms :A list of definitions and notes on pain.1979; 6:249
2. W.Paul, Farquhar Smith .Anatomy, physiology and pharmacology of pain. Anasthesia and Intensive care medicine. 2008;9:3-7.
3. Kehlet H. Effect of postoperative pain treatment on outcome :Current status and future strategies. Langenbecks Arch Surg. 2004;389:244–49.
4. White PF, Kehlet H. Improving postoperative pain management: What are the unresolved issues? Anesthesiology. 2010;112:220–25.
5. Apfelbaum JL, Chen C, Mehta SS, Gan TJ. Postoperative pain experience: Results from a national survey suggest postoperative pain continues to be undermanaged. Anesth Analg. 2003;97:534–40.
6. White PF. Pain management after ambulatory surgery, where is the disconnect? Can J Anaesth. 2008;55:201–207.
7. Kehlet H, Holte K. Effect of postoperative analgesia on surgical outcome. Br J Anaesth. 2001;87:62–67.
8. Rigg JR, Jamrozik K, Myles PS. Epidural anaesthesia and analgesia and outcome of major surgery: A randomized trial. Lancet. 2002; 359: 1276.
9. Stienstra R .The place of ropivacaine in anesthesia. Acta Anaesthesiol Belg.2003; 54: 141-48.
10. Agarwal A, Verma RK, Srivastava S . Ropivacaine: The latest local anesthetic in the Indian Market. J Anesth Clin Pharmacol. 2010; 26: 223-28.
11. Vieira AM, Schnaider TB, Brandao AC, Pereira FA, Costa ED, Fonseca CE. Epidural clonidine or dexmedetomidine for post-cholecystectomy analgesia and sedation. Rev Bras Anesthesiol. 2004;54: 473-78.
12. Gupta R, Kaur S, Singh S, Aujla KS. A comparison of epidural butorphanol and tramadol for postoperative analgesia using CSEA technique. J Anaesthesiol Clin Pharmacol. 2011;27:35.
13. Bajwa SJ, Bajwa SK, Kaur J, Singh G, Arora V, Gupta S, et al. Dexmedetomidine and clonidine in epidural anaesthesia: A comparative evaluation. Indian J Anaesth. 2011;55:116.
14. Coskuner I, Tekin M, Kati I, Yagmur C, Elcicek K. Effects of dexmedetomidine on the duration of anaesthesiaand wakefulness in bupivacaine epidural block. Eur J Anaesthesiol. 2007;24:535
15. Selim MF, Elnabtity AM, Hasan AM. Comparative evaluation of epidural bupivacaine-dexmedetomidine and bupivacaine fentanyl on doppler velocimetry of uterine and umbilical arteries during labor. J Prenat Med. 2012;6:47.
16. Kanazi GE, Aouad MT, Jabbour Khoury SI, Al Jazzar MD, Alameddine MM, Al Yaman R, et al. Effect of low dose Dexmedetomidine or clonidine on the characteristics of bupivacaine spinal block. Acta Anaesthesiol Scand. 2006;50:222–7.
17. Taenzer AH, Clark C. Efficacy of postoperative epidural analgesia in adolescent scoliosis surgery: A metaanalysis. Paed Anaesth. 2010;20: 135–43.
18. Farmery AD, WilsonMacDonald J. The analgesic effect of epidural clonidine after spinal surgery: A randomized placebocontrolled trial. Anesth Analg. 2009;108:631.
19. Kumar RJ, Menon KV, Ranjith TC. Use of epidural analgesia for pain management after major spinal surgery. J Orthop Surg .2003;11:67
20. Pichot C, Longrois D, Ghignone M, Quintin L. Dexmedetomidine and clonidine: A review of their pharmacodynamy to define their role for sedation in intensive care patients. Ann Fr Anesth Reanim. 2012; 31:876.
21. ElHennawy AM, AbdElwahab AM, AbdElmaksoud AM, ElOzairy HS, Boulis SR. Addition of clonidineor dexmedetomidine to bupivaacaine prolongs caudalanalgesia in children. Br J Anaesth. 2009;10(3):268–74