Original Research Article

Comparative Evaluation of Epidural Clonidine and Dexmedetomidine in Post Operative Analgesia

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ABSTRACT

Background and Aims: Clonidine and dexmedetomidine are α -2 adrenergic agonists with analgesic proprieties which potentiate local anesthetic effects when epidurally administered.

The present study was undertaken with following aims: 1. To compare onset & duration of analgesia, incidence of side effects and complications of epidural clonidine and dexmedetomidine in post operative analgesia. 2. To study the potentiating effect of epidural clonidine /dexmedetomidine associated with ropivacaine (0.2%)

3. To know hemodynamics related to epidural clonidine and dexmedetomidine.

Materials & Methods: After taking institutional approval and consent from patients, the study was carried out on 60 patients of A.S.A. grade I and grade II between 18-50 years. All patients were divided into two groups group 1 and 2 randomly.

Group -1: received Ropivacaine 0.2% plus clonidine 1 mcg/kg

Group -2: received Ropivacaine 0.2% plus dexmedetomidine 1 mcg/kg.

Result: Statistically significant values were observed on comparison of post-operative block characteristics among the two groups (p < 0.001), both for time to two segment regression and time for first rescue top-up. Dexmedetomidine provided a smooth and prolonged post-operative analgesia as compared to clonidine. There was significant change in VAS score at 5 and 10 min post injection of drug in both groups as p value is <0.001 (very highly significant) at both time intervals, but mean VAS sore were higher in clonidine group in comparison to Dexmedetomidine group. There was decreasing trend of mean Pulse rate after 4 hours post injection & this decrease was very highly significant in the RC group (group 1) compared to RD group (group 2). The incidence of dry mouth was significantly higher in both the groups but it was statistically non-significant on comparison (P > 0.05).

Conclusion: Dexmedetomidine is a better adjuvant than clonidine in epidural post operative analgesia as far as patient comfort, stable cardio-respiratory parameters, and post-operative analgesia is concerned.

Keywords: Dexmedetomidine, clonidine, ropivacaine, post-operative analgesia, gynecological surgeries.

INTRODUCTION

The pharmacologic properties of α -2 agonists as lumbar/thoracic epidural adjuvants have been studied vastly and been used clinically to achieve the desired effects in regional anesthesia. ^[1,2]

Dexmedetomidine is a selective α -2 adrenergic agonist with a 1600 greater selectivity for the α -2 receptor compared with the α -1 receptor.

Dexmedetomidine has been approved as a short-term sedative for adult intubated patients in the ICU. Given its well-documented beneficial effects of sedation, anxiolysis, analgesia, and sympatholysis with minimal respiratory depression, it also has been used in various other clinical scenarios.

For sedation in the ICU, loading doses of 0.5 to 1 μ g/kg have been used. Infusion rates of 0.1 to 1 μ g/kg/hr are generally needed to maintain adequate sedation. Delirium in the ICU is a risk factor for increased length of stay and increased mortality.

a premedicant, dexmedeto-As midine, at IV doses of 0.33 to 0.67 µg/kg given 15 minutes before surgery, seems minimizing efficacious. while the cardiovascular side effects of hypotension and bradycardia. Within this dosage range, dexmedetomidine reduces thiopental requirements (by ±30%) for short procedures, reduces the requirements of volatile anesthetics (by $\pm 25\%$), and more effectively attenuates the hemodynamic response endotracheal intubation to compared with 2 µg/kg of fentanyl. Dexmedetomidine (1 µg/kg given over 10 minutes) when used for intraoperative sedation resulted in a slower onset than propofol (75 µg/kg/min for 10 minutes), but similar cardiorespiratory effects when titrated to equal sedation. The average dexmedetomidine infusion rate of intraoperatively to maintain a BIS value of 70 to 80 was 0.7 μ g/kg/min.

For maintenance of anesthesia, dexmedetomidine has been used in patients undergoing multiple types of surgery. In patients given an infusion regimen to achieve a plasma concentration of slightly less than 1 ng/mL, combined with 70% nitrous oxide, dexmedetomidine reduced isoflurane requirements by 90% compared with a control group.

Dexmedetomidine is eight times more selective α -2 adrenoceptor agonist emerging as a valuable adjunct to regional anaesthesia and analgesic. Based on earlier human

studies, it is hypothesized that intrathecal Dexmedetomidine would produce more post-operative analgesic effect with minimal side effect. ^[3,4]

Clonidine is highly lipid soluble and readily penetrates the blood-brain barrier and the placenta. Studies indicate that binding of clonidine to receptors is highest in the rostral venterolateral medulla in the brain stem (the final common pathway for sympathetic outflow) where it activates inhibitory neurons. The overall effect is to decrease sympathetic activity, enhance parasympathetic tone. and reduce circulating catecholamines. There is also that evidence much of clonidine's antihypertensive action occurs via binding to a nonadrenergic (imidazoline) receptor. In contrast, its analgesic effects, particularly in the spinal cord, are mediated entirely via pre- and possibly postsynaptic 2-adrenergic receptors that block nociceptive transmission.

Clonidine is a commonly used antihypertensive agent, but in anesthesia it is used as an adjunct for epidural infusions in pain management. It is most useful in the management of patients with neuropathic pain who become increasingly resistant to epidural opioid infusions. When given epidurally, the analgesic effect of clonidine is segmental, being localized to the level at which it is injected or infused. When used for the acute or chronic management of hypertension, the reduction in sympathetic tone decreases systemic vascular resistance, heart rate, and blood pressure.

Epidural clonidine is usually started at 30 µg/hr in a mixture with an opioid and/or local anesthetic. Oral clonidine is readily absorbed, has a 30-60 min onset, and lasts 6-12 hr. In the treatment of acute hypertension, 0.1 mg can be given orally every hour until the blood pressure is controlled, or up to a maximum of 0.6 mg; the maintenance dose is 0.1-0.3 mg twice a day. Transdermal preparations of clonidine can also be used for maintenance therapy. They are available as 0.1, 0.2, and 0.3 mg/day patches that are replaced every 7

days. Clonidine is metabolized by the liver and excreted renally. Dosages should be reduced for patients with renal insufficiency.

Clonidine enhances and prolongs sensory and motor blockade from epidural local anesthetics. Additive effects with hypnotic agents, general anesthetics, and sedatives can potentiate sedation, hypotension, and bradycardia. The drug should be used cautiously, if at all, in patients on adrenergic blockers and in those with significant cardiac conduction system abnormalities. Lastly, Clonidine can mask the symptoms of hypoglycemia in diabetic patients.

The adverse effect of postoperative pain are many, but can be minimized by pain therapy. Patient with significant pain may show insomnia, restlessness, anxiety and helplessness. In the modern postoperative care, this means effective relief of pain, anxiety, suffering and insomnia.

The postoperative pain relief is largely unsolved medical problem and has driven most anesthesiologists to a state of therapeutic nihilism exemplified by prescription of intramuscular opioids.

The present study was undertaken with following aims:

1. To compare onset & duration of analgesia, incidence of side effects and complications of epidural clonidine and dexmedetomidine in post operative analgesia.

2. To study the potentiating effect of epidural clonidine /dexmedetomidine associated with ropivacaine (0.2%)

3. To know hemodynamics related to epidural clonidine and dexmedetomidine.

MATERIALS AND METHODS

The present study was carried out on 60 patients of A.S.A. grade I and grade II between 18 - 50 years and of both sex who has undergone different types of lower limb and gynaecological surgeries in L.L.R. and Associate Hospital, Kanpur. Consent was

taken from the patients before their selection of trial.

Exclusion Criteria:

i. Patients other than A.S.A. grade I and grade II.

ii. Patients with age <18 years and >50 years.

iii. Any major systemic illness(Uncontrolled Diabetes, Hypertension, Ischemic Heart Disease, significant Respiratory disease, etc.).

iv. Contraindication to Epidural Anaesthesia (any bleeding disorder, spinal deformity, sepsis at local site, etc.)

v. Pregnancy and severe anaemia

vi. History of allergy to the drugs used in the study

All patients were divided into two groups group 1 and 2 randomly.

Group -1 (RC group): received Ropivacaine 0.2% plus clonidine 1 mcg/kg

Group -2 (RD group): received Ropivacaine 0.2% plus dexmedetomidine 1 mcg./kg.

Anaesthesia technique:

All the patients were operated under spinal anesthesia using 0.5% Bupivacaine.

The patients were inserted intravenous cannula into a peripheral vein and were preloaded with 500 - 1000 ml of Ringer Lactate solution prior to initiation of spinal anaesthesia. Lignocaine sensitivity was done by 0.2 ml intradermal 2% Lignocaine. After part preparation, epidural catheter was introduced in sitting position in L3 - L4 or L2 - L3 intervertebral space with a 16 G Touhy epidural needle. Epidural space was recognized by 'Loss of Resistance' technique. Aspiration test for C.S.F. and blood was done. Epidural Catheter of 18 G was inserted in epidural space through the Tuohy needle upto mark III then the needle was removed and catheter pulled upto 7cms. Test dose 3ml Lignocaine with Adrenaline (1:200,000) was injected. The catheter was then anchored in place on the back of patient and made supine position of patient.

After assessing the effect of test dose and confirmation of epidural catheter placement local anaesthetic given was 3 ml

of 0.5% Bupivacaine was given intrathecally. No narcotics or NSAIDS were administered throughout the intraoperative period.

Post operative period:

After the surgery patient was shifted to post operative room and monitoring was continued.

Once the patient in the post operative room, complaint of pain (Visual analogue scale of 4 or more), the study was begun and the patient were randomly divided into two groups to receive following drugs through epidural route by blind observation.

Group -1: received Ropivacaine 0.2% plus clonidine 1 mcg/kg

Group -2: received Ropivacaine 0.2% plus dexmedetomidine 1 mcg./kg.

After the drug was given the following parameters were noted by independent observer-

1. Onset of analgesia

2. The pain score, by using visual analogue scale

3. Duration of analgesia

4. Upper level of analgesia

5. Monitoring of vital parameters like Blood pressure, pulse rate, respiratory rate

6. Side effects like nausea, vomiting, respiratory depression, numbress, shivering and hypotension.

The degree of pain relief was assessed by the patient and the observer. Since pain perception was highly subjective from individual to individual, this variable was standardized by using data from visual linear analogue scale.

As mentioned earlier, this involves the use of 10 cm line on a piece of white paper. The patients were once again explained to that one end of line represents no pain (0 cm) and other end of line represents the worst possible pain patient can imagine (10 cm). Patients were asked to the rate of degree of pain by marking it on the scale.

The patient was shown a 10 cm scale marked as above. They were asked to put a mark across the line that indicates the severity of their pain. Pain was further graded as -

0 - (VAS 0) Patient is comfortable.

1 - (VAS 1-3) Mild pain.

2 – (VAS 4-6) Moderate pain

After the drug was given epidural, the time of onset of pain relief was noted along with blood pressure, heart rate and respiratory rate, which were measured every 5 minutes for half hour and every half hour after that.

The intensity of pain on Visual analogue scale every hour and duration of action to reach Visual analogue scale of 6 cm was noted for patients in both groups. The time taken for VAS to reach 4 from the time of intrathecal injection of the drug or for the patents to request for the further analgesia from the time of injection of the drug was taken as duration of action of the drugs for the particular group.

Statistical Analysis:

All statistical analyses were performed using INSTAT for windows. Continuous variables were tested for normal distribution by the Kolmogorov-Smirnov test. Data were expressed as either mean and standard deviation or numbers and percentages. Demographic data were compared using student's unpaired t test. The monitored and calculated parameters were analysed using Student's unpaired t test and paired t test. For all statistical analysis, the value of p<0.05 was considered significant and value of p<0.001 was considered as highly significant.

RESULT

Та	ble 1.	Distribution of patient	
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Group	No. Of	Drug	Epidural
	Patient	Administration	Dose
RD Group	30	Ropivacaine (0.2%)	20 mg
_		Dexmedetomidine	50 µg
RC Group	30	Ropivacaine (0.2%)	20 mg
		Clonidine	50 µg

Table 2: Mean Age and Weight of patients.

	RD Group	RC Group	P value
	(mean±SD)	(mean±SD)	
Age	40±8.146	38±6.26	0.3006
Weight	52±6.50	50±2.46	0.1204

Table 2 shows the mean age and weight in both the groups, which are almost

comparable with each other as p value is >0.05 which is not significant.

T	Table 3: Showing Sex Distribution Of Patients.						
	Sex	RD C	iroup	RC G	roup		
	Distribution	No.	%	No.	%		
	Male	14	46.67	13	43.33		
	Female	16	53.33	17	56.67		

Table 3 shows distribution of sex patterns in the study, which reveals nearly comparable percentage of patients of both sex undergoing in each group, receiving epidural drug administration in postoperative period.

Table 4: Onset of Analgesia						
Initial block characteristics	Group RD $(n = 30)$	Group RC	p value			
		(n = 30)				
Onset time of sensory block at T10 (in minutes)	8.00±0.85	9.02 ± 3.44	0.120			
Time to maximum sensory block level (in minutes)	13.14±3.96	15.80 ± 4.86	0.018			

Table 4 shows addition of Dexmedetomidine to Ropivacaine as an adjuvant resulted in an earlier onset $(8.00 \pm 0.85 \text{ min})$ of sensory analgesia at T10 as compared to the addition of clonidine (9.02 $\pm 3.44 \text{ min})$ but this difference is not significant as p value is more than >0.05

(0.120). Dexmedetomidine not only provided a higher dermatome spread but also helped in achieving the maximum sensory anesthetic level in a shorter period (13.14 \pm 3.9min) compared to clonidine (15.80 \pm 4.86), this difference is significant as p value is <0.05 (0.018).

Table 5: Duration of Analgesia (Comparison of block characteristics)							
Block characteristics (in minutes)	Group RD	Group RC	P valve				
Mean time to two segmental regression	156.46 ± 8.12	128.08 ± 7.54	< 0.0001				
Mean time to sensory regression at S1	346.64 ± 40.36	296.72 ± 35.52	<0.0001				
Time to first rescue top-up	420.88 ± 29.16	340.76 ± 23.76	< 0.0001				

The findings of table 5 reveal statistically significant values on comparison of postoperative block characteristics among the two groups because p value is < 0.001, both for time to two segment regression and time for first rescue top-up. Dexmedetomidine provided a smooth and prolonged postoperative analgesia as compared to clonidine. The evidence was very much visible in the prolonged time to two segmental dermatome regression (156.46 \pm 8.12 min). As a result the time for rescue analgesia was comparatively shorter (340.76 \pm 23.75 min) in the patients who were administered clonidine.

			Table 6: V	AS Score	Obser	vation			
GROUP	0 min	5min	10min	30 min	2 hr	4 hr	6 hr	8hr	9 hr
RD	7.1±1.0	3.8±1.87	0.8±0.92	0	0	0	2.7±0.95	5.5±1.08	7.2±0.92
RC	7.3±1.06	5.7±0.8	1.5±0.87	0	0	0	4.6±1.07	6.5±1.26	8.0±0.94
P value	0.455	< 0.001	0.0037	0	0	0	< 0.001	0.0017	0.0015



Table 6 and figure 1 show VAS score at different time intervals. This revealed that there is significant change in VAS score at 5 and 10 min post injection of drug in both groups as p value is <0.001 (very highly significant) at both time intervals, but mean VAS sore were higher in clonidine group in comparison to Dexmedetomidine group. In both the groups, there is increasing trend of mean VAS score after 6 and 8 hrs post injection of the drug. But still mean VAS sore were higher in clonidine group in comparison to

Dexmedetomidine group, different time intervals.

	Table 7. Showing mean pulse rate change per minute at unrerent intervals in unrerent groups.						
	Drug delivered	Immediate post injection	Post injection at 1 Hr	2 Hrs	4 Hrs	6 Hrs	8 Hrs
	0 Hrs	30 min	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD
	Mean±SD	Mean±SD					
Group RD	90.80±8.71	81.80±3.72	79.80±3.36	79.40±1.31	82.80	88.20	88.00
					±4.60	±9.70	±9.00
Group RC	90.30±6.06	84.80±3.69	82.20±3.03	80.80±4.51	79.60	78.40	78.80
					±4.66	±6.05	±3.39
P value	0.7972	0.0027	0.0006	0.2483	<.0001	<.0001	<.0001

Table 7: Showing mean pulse rate change per minute at different intervals in different groups.

Table 7 shows that there was no significant difference of pulse rate in both the groups at the time of administration of drugs but it started to decrease as evident that at 30 min post injection, the p value is <0.01 which is highly significant. There is decreasing trend of mean Pulse rate after 4

hours post injection & this decrease was very highly significant in the RC group compared to RD group. There was decrease in Pulse Rate in both groups after giving the drug but none of patient showed bradycardia at any time.

Table 8: Showing Mean Systolic Blood Pressure Change In mmHg At Different Intervals In Different Groups

	Drug	Immediate post	Post injection at 1				
	delivered	injection	Hr	2 Hrs	4 Hrs	6 Hrs	8 Hrs
Group	0 Hrs	30 min	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD
	Mean±SD	Mean±SD					
Group	121.40 ±9.97	121.30 ±4.11	118.40 ±4.79	119.40	123.50	123.90	118.30
RD				±3.18	±6.38	±8.16	±4.91
Group	122.60 ± 8.08	119.90	120.10	119.80	121.10	120.30	123.00
RC		±6.94	±3.64	±5.80	±5.67	±4.19	±3.86
P value	0.63	0.95	0.128	0.74	0.129	0.036	0.0001

Table 8 shows that, there was no significant change in systolic blood pressure after giving the drug in both group. But significant change was noticed after 4 hours post injection, between two groups.

 Table 9: Comparison of side effects observed in both the groups during and after the operative period.

Side effects	Group RD	Group RC
Nausea	5	4
Vomiting	1	1
Shivering	1	2
Headache	1	1
Dizziness	3	2
Dry mouth	7	8
Respiratory depression	0	0

Table 9 shows the comparative incidence of various side effects in both the groups which were observed in post injection period. The incidence of dry mouth was significantly higher in both the groups but it was statistically non-significant on comparison (P >0.05). The incidence of other side effects like nausea, vomiting, headache, shivering and dizziness were comparable in both the groups and statistically non-significant. There was no

respiratory depression in any patient from either group.

DISCUSSION

Main aim of post operative pain relief is to provide subjective comfort, in addition to inhibiting nociceptive impulses caused by trauma and to blunt autonomic as well as somatic reflexes to pain. Subsequently, this will enhance restoration of function by allowing the patient to breathe, cough and to be easily ambulant.

Our present study compared the effects of single dose of epidural mixture of Ropivacaine with Dexmedetomidine and Clonidine separately, in postoperative periods.

The use of neuraxial opioids is associated with quite a few side effects, so various options including α -2 agonists are being extensively evaluated as an alternative with emphasis on opioid-related side effects such as respiratory depression, nausea, urinary retention and pruritus. In study conducted by Arain SR et al ^[5] concluded

that the use of dexmedetomidine for postoperative analgesia resulted in significantly less additional pain medication (morphine) and slower heart rates than a control group receiving only morphine.

The pharmacologic properties of α -2 agonists have been extensively studied and have been employed clinically to achieve the desired effects in regional anesthesia. In article published by Gabriel JS et al, ^[6] clonidine can provide pain relief by an opioid-independent mechanism. It has been shown to result in the prolongation of the sensory blockade and a reduction in the amount or concentration of local anesthetic required to produce perioperative analgesia. Most authors agree that the use of clonidine for regional neural blockade in combination with a local anesthetic results in increased duration of sensory blockade with no difference in onset time. The higher doses of clonidine were associated with a more cephalad spread of the spinal blockade.

Epidural administration of these drugs is associated with sedation, analgesia, anxiolysis, hypnosis and sympatholysis. Clonidine has been used successfully over the last decade for the said purpose and the introduction of dexmedetomidine has further widened the scope of α -2 agonists in regional anaesthesia. The faster onset of action anaesthetics, of local rapid establishment of both sensory and motor blockade, prolonged duration of analgesia into the post-operative period, dose-sparing action of local anaesthetics and stable cardiovascular parameters makes these agents a very effective adjuvant in regional anaesthesia.

The present study was undertaken to compare the analgesic efficacy in postoperative periods. The demographic profile of our patients was comparable with respect to mean age, body weight as shown in Table 2, ASA grade. The selection of the patients was comparable to study conducted by Vieira AM, Schnaider TB et al (2004).^[7]

Dexmedetomidine has a visible edge over clonidine as it enables an earlier onset and establishment of sensory and motor

block. Further, addition of these two adjuvants promotes faster onset compared to established time of onset of sensory analgesia with ropivacaine alone. The results of Table 4 show the early onset of analgesia in Dexmedetomidine group than in clonidine group. These results are similar to study conducted by Sukhminder J.S. Bajwa et al, ^[8] but these results are not matching with study conducted by Antônio Mauro Vieira, Taylor Brandão et al (2004), [7] in their study although clonidine or dexmedetomidine associated to ropivacaine have promoted analgesia and sedation at 2 and 6 hours after anesthetic recovery in submitted patients subcostal to cholecystectomy, but clonidine group shows higher anesthesia time than dexmedetomidine group, be this can because they have used 2mcg/kg of clonidine as compared to our study ,this dose is just double as we have used in present study.

The results of the Table 5 has shown that the addition of either $1.0 \ \mu g/kg$ dexmedetomidine or 1 μ g/kg clonidine as adjuvant to epidural ropivacaine prolongs the duration of analgesia which is similar to the findings of Elhakim M et al. ^[9] Present result is also similar to study conducted by Klimscha et al. ^[10] who had studied the effectiveness of caudal clonidine in potentiating the post-operative analgesic effect and found that in small children with a mean age of 3 years who underwent an elective day care surgery for hernia operations, the addition of clonidine 1-2 ug/kg to bupivacaine significantly prolonged the median duration of analgesia and reduced the total dose of post-operative analgesics compared with bupivacaine alone. Maximum duration of block in our study is higher in RD group than in RC group, this result is also comparable to study conducted by Sukhminder J.S. Bajwa et al. [8]

Table 6 shows VAS score at different time intervals. This revealed that there is significant change/ decrease in VAS score at 5 and 10 min post injection of drug

in both groups as p value is <0.001 (very highly significant) at both time intervals, but mean VAS sore were higher in clonidine group in comparison to Dexmedetomidine group. In both the groups, there is increasing trend of mean VAS score after 6 and 8 hrs post injection of the drug. But still mean VAS sore were higher in clonidine group in comparison to Dexmedetomidine group in comparison to Dexmedetomidine group, different time intervals. Our findings are consistent with other studies conducted by Cucchiaro G et al ^[11] and Andrew D. Farmery. ^[12]

The RD group showed visible superiority over RC group in various postoperative block characteristics like the weaning of sensory block, prolonged postoperative analgesia and a lesser amount of total ropivacaine used post-operatively. The cardio-respiratory parameters remained stable throughout the study period which reaffirms the established effects of α -2 agonists in providing a haemodynamically stable peri-operative and post-operative period.

A slight decrease in heart rate and mean arterial pressure was observed in both the groups as shown in Table 8 & Table 9, it never fell down to more than 15% of the baseline values. The results was comparable to a study conducted by A. M. El-Hennawy, A. M. Abd-Elwahab et al ^[13] found that the magnitude of hemodynamic changes between the groups was comparable and therapeutic interventions were not required.

The side effect profile of both these drugs was quite favourable as none of the patient in either group had pro-found deep sedation or respiratory depression which correlates very well with other studies like the study conducted by A. M. El-Hennawy, A. M. Abd-Elwahab et al ^[13] found that the addition of dexmedetomidine or clonidine to bupivacaine did not result in an increase in the incidence of side-effects. Moreover, the magnitude of haemodynamic changes between the groups was similar.

Although we observed a little higher incidence of dry mouth and nausea in both the groups as shown in Table 9, it was only mildly discomforting to the patients and was mainly observed in the post-operative period and non-significant on statistical comparisons. These results are similar to study conducted by S. J.S. Bajwa, S. Kaur Bajwa et al ^[8, 14] in which they found incidence of dry mouth comparable to present study.

CONCLUSION

Our study concluded that epidural ropivacaine 0.2% with either 50 microgram of dexmedetomidine or clonidine in a total volume of 10.5 ml can provide excellent post operative analgesia for the patient who underwent lower limbs and gynecological surgeries.

We concluded that dexmedetomidine is a better adjuvant than clonidine in epidural post operative analgesia as far as patient comfort, stable cardio-respiratory parameters, and post-operative analgesia is concerned, as evident from the study that Dexmedetomidine group achieved earlier onset of analgesia, longer duration of analgesia and lower scores of pain at different time intervals expressed in mean of VAS.

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