A COMPARATIVE STUDY OF POST-OPERATIVE CONTINUOUS WOUND INFILTRATION WITH DEXMEDETOMIDINE - ROPIVACAINE MIXTURE AND PLAIN ROPIVACAINE IN PATIENTS UNDERGOING LUMBAR SPINE SURGERIES

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ABSTRACT

BACKGROUND

Various adjuvant used along with Local Anaesthetics [LA] to increase post-operative analgesia. Dexmedetomidine is a new highly selective α_2 adrenergic agonist adjuvant. The objective of our study is to compare the duration of post-operative analgesia and sedation effect of dexmedetomidine - ropivacaine mixture with ropivacaine alone.

Settings and Design - Tertiary level, teaching hospital. Prospective randomised double-blind study case control study.

MATERIALS AND METHODS

50 patients aged between 20 to 60 years of age of ASA Grade 1 and 2 undergoing elective spine surgeries were randomly allocated into two groups of 25 patients each. Patients in Group D receives dexmedetomidine 50 μ g + 0.25% ropivacaine 14 mL total of 15 mL as bolus and followed by dexmedetomidine + 0.25% ropivacaine mixture infusion at 5 mL/hr. (100 μ g of (1 mL) dexmedetomidine in 49 mL 0.25% Ropivacaine) as continuous infusion through an 18-G epidural catheter. Group R receives 0.25% ropivacaine 14 mL + 1 mL of normal saline total of 125 mL as bolus and followed by 0.25% ropivacaine 5 mL/hr. as continuous infusion through an epidural catheter in the post-operative period for the first 24 hrs. Time of bolus dose is taken as zero. Infusion was discontinued after 24 hrs. and catheter removed and dressing done. Besides cardiorespiratory parameters and sedation scores, Visual Analogue Score (VAS), Time of Rescue Analgesia and Total Amount of Rescue Analgesia was compared in each group. At the end of study, data was compiled systematically and analysed using ANOVA with post-hoc significance, Chi-square test and Fisher's exact test. Value of $P < 0.05$ is considered significant and $P < 0.001$ as highly significant.

RESULTS

Significantly onset of action is rapid in Group 1 patients, where dexmedetomidine - ropivacaine mixture is used as compared to control group. Average time of onset of action in Group 1 is 8.16 ± 2.5 mins. compared to 13.6 ± 4.1 in Group 2. A higher number of patients in control group has requested for rescue analgesia in the post-operative period than Group 1 patients. Average time for first request of rescue analgesia in Group 1 patients is 312.2 ± 16.1 mins. compared to 156.2 ± 12.6 mins. in control group. Sedation effect was found to be better in Group 1 patients as compared to control group.

CONCLUSION

It was concluded that dexmedetomidine used as an adjuvant to ropivacaine in surgical wound infiltration for post-operative analgesia in patients undergoing spine surgeries provides longer duration of post-operative pain relief compared to ropivacaine alone.

KEYWORDS

Dexmedetomidine, Ropivacaine, Surgical Wound Infiltration, Analgesia, Sedation, Spine Surgery.

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BACKGROUND

Relieving post-operative pain of spine surgeries has become an indispensable component in anaesthesia. Various methods have been tried for the management of post-operative pain in spine surgeries; α_2 adrenergic agonists have both analgesic and sedative properties when used as an adjuvant in regional anaesthesia.^[1]

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Dexmedetomidine is a highly selective α_2 adrenergic agonist with receptor affinity 8 times greater than clonidine.^[2] The degree of pain relief increases with the addition of alpha agonist to epidural local anaesthetics, because of their analgesic properties and augmentation of local anaesthetic effects.^[3] Use of adjuvant also minimises the adverse effects of dose of local anaesthetics and also decreases the doses of opioid analgesics. Dexmedetomidine is reported to have a synergetic effect with ropivacaine in providing post-operative analgesia. Based on earlier studies, dexmedetomidine produces prolonged post-operative analgesia and sedation with minimal side effects when added to ropivacaine in epidural and caudal anaesthesia. Since very few studies available where dexmedetomidine's efficacy as an adjuvant to ropivacaine in surgical wound infiltration has been explored. So we planned a prospective double-blind study to explore the efficacy of dexmedetomidine as an adjuvant to ropivacaine in terms of duration of sensory block and to produce sedation.

MATERIALS AND METHODS

This prospective randomised double-blind study was conducted after approval from Institutional Ethical Committee and informed and written consent of patients; 50 patients aged between 20 - 60 years of age belonging to ASA Grade 1 and 2 scheduled for elective spine surgeries randomised into two groups of 25 patients each by computerised randomisation technique. At the end of surgery once skin closure was done, an epidural catheter tunnelled into subcutaneous tissue at centre of the wound with the help of 18-G Tuohy needles and the catheter secured with tunnelling to normal skin. Bolus dose of study drug was given on the operation table and infusion of analgesic mixture started in the post-operative ward through a syringe pump.

Patients in Group D received dexmedetomidine 50 µg + 0.25% ropivacaine 14 mL total of 15 mL as bolus and followed by dexmedetomidine + 0.25% ropivacaine mixture infusion at 5 mL/hr. (100 µg of (1 mL) dexmedetomidine in 49 mL 0.25% Ropivacaine).

Group R receives 0.25% ropivacaine 14 mL + 1 mL of normal saline total of 15 mL as bolus and followed by 0.25% ropivacaine 5 mL/hr.

Infusion discontinued after 24 hrs. and catheter was removed and redressing was done. All the patients were explained Linear Visual Analogue Scale (LVAS) scoring system of pain assessment in post-operative ward.^[4] The LVAS used a 10 cm scale, where 0 denotes 'no pain,' while 10 denotes worst pain and sedation was assessed using Ramsay sedation scale.^[5] The VAS score at rest was noted at 1, 3, 6, 9, 12 and 24 hours. Time to demand the first rescue analgesia was recorded. Vital signs and time of first demand for rescue analgesia was recorded. In the post-operative period heart rate, systolic blood pressure, diastolic blood pressure, respiratory rate, SpO₂ were also recorded at 1, 3, 6, 9, 12 and 24 hours after operation.

Statistical Analysis

The sample size was calculated on the basis of assuming a difference of VAS of 20 mm in the combination group of ropivacaine and dexmedetomidine as compared to ropivacaine alone. Data are expressed as numbers; percentages, median or mean ± SD. Demographic and haemodynamic parameters as well as doses of drugs administered were analysed and compared by using student's t-test. The number of patients receiving rescue Inj. Paracetamol 1000 mg IV as well as the incidence of nausea, vomiting, dizziness, drowsiness and fever was analysed by using Fisher's exact test. Patient-generated VAS was analysed with the Mann-Whitney U-test. In all cases, P < 0.05 was considered to be statistically significant.

RESULTS

A total of 50 patients who underwent spine surgery were enrolled for the study and were randomly divided into two groups. The demographic profiles of the patients in both the groups were comparable with regards to age, weight and body mass index. The distribution as per ASA status was similar in both the groups and mean duration of surgery was comparable in both the groups and statistically non-significant (P > 0.05) [Table 1].

Parameter	Group 1	Group 2	P value
Age (yrs.)	42.76±3.4	43.41±2.7	NS
Gender (m:f)	17:8	19:6	NS
Weight (kg)	63.54±6.2	69.71±4.9	NS
ASA I:II	9:16	11:14	NS
Duration of Surgery (min.)	112.6±9.6	119±7.4	NS

Table 1. Demographic Profile in the Three Groups

Addition of dexmedetomidine to ropivacaine as an adjuvant resulted in an earlier onset (8.16±2.5 mins.) of sensory analgesia at T10 as compared to the ropivacaine group (13.6±4.1 mins). Characteristics turned out to be statistically significant values on comparison (P < 0.001) [Table 2].

Parameter	Group 1	Group 2	P value
Time (min)	8.16±2.5	13.6±4.1	0.0007

Table 2. Onset Sensory Block

Time (hr.)	Group D	Group R	P value
1	7	7	NS
3	6.5	6	NS
6	6	6	NS
9	6	5.5	NS
12	5.5	5	NS
24	5	4	NS

Table 3. Visual Analogue Score

Dexmedetomidine is a popular sedative agent nowadays and similar findings were observed in our study as well. Mean sedation scores were significantly higher in RD group compared to RC group, as 36% patients in Group D had a sedation score of 3 as compared to 16% in Group R (P < 0.0001). Only 16% of the patients in the D Group had sedation scores of 1 compared to 32% wide and awake patients in R Group, which was a highly significant statistical entity (P < 0.0001) Table 4.

Sedation Scores	Group D No. of Patients/(%)	Group R No. of Patients/(%)	P
1	4 (16)	8** (32)	< 0.0001
2	12 (48)	13 (52)	0.65
3	9** (36)	4 (16)	< 0.0001
4	0	0	-
5	0	0	-

Table 4. Post-Operative Sedation Scores

Table 5 shows the comparative incidence of various side effects in both the groups, which were observed in the intra-op and post-op period. The incidence of other side effects like nausea, vomiting, headache, shivering and dizziness were comparable in both the groups and statistically non-significant. We did not observe the respiratory depression in any patient from either group.

Side Effects	Group D (n = 25)	Group R (n = 25)
Nausea	4 (16)	3 (12)
Vomiting	1 (4)	1 (4)
Shivering	1 (4)	2 (8)
Headache	1 (4)	1 (4)
Dizziness	3 (12)	2 (8)
Bradycardia (< 60 beats/min)	11	0

Table 5. Post-Operative Adverse Events

Significantly, onset of action is rapid in Group D patients compared to control group. Sedation effect is significantly better in dexmedetomidine – ropivacaine group compared to ropivacaine alone. Control group patients required rescue analgesia earlier than Group 1 patients in the post-operative period on second post-operative day after infusion stopped. The average time for first request for rescue analgesia were 312.2 ± 16.1 mins. and 156.2 ± 12.7 mins. in Group 1 and Group 2 respectively; 7 out of 25 patients in control group requested for rescue analgesia during first 24 hrs. of post-operative period. Rescue analgesia was fulfilled with Inj. Paracetamol 1 gm IV stat.

DISCUSSION

The use of opioids^[6] along with local anaesthetics to prolong the duration of post-operative analgesia is associated with number of side effects such as vomiting, nausea, pruritus and urinary retention. Hence, other adjuvants like α_2 agonist such as dexmedetomidine are extensively used as an alternative to opioids. Early onset of analgesia, prolonged analgesia and sedation effect of dexmedetomidine is due to its highly selective α_2 agonistic affinity and its greater lipid solubility helps in easy penetration. The synergistic action of dexmedetomidine^[7] with local anaesthetics is because they cause hyperpolarisation of nerve tissues at the level of locus coeruleus in the brain stem. The analgesic effect of dexmedetomidine is due to inhibition of release of substance P in the nociceptive pathway and also inhibits the release of norepinephrine at the nerve endings.

Kim BG, Kang H compared the effect of pre-emptive perianal Ropivacaine and Ropivacaine with Dexmedetomidine on pain after haemorrhoidectomy and concluded that the use of perianal ropivacaine injection prior to surgical incision reduced both postoperative pain and fentanyl consumption following haemorrhoidectomy and the addition of dexmedetomidine to ropivacaine may have an additive effect in postoperative analgesic care, which is similar to this study.^[8]

Vinson-Bonnet et al previously reported that perianal infiltration of ropivacaine, improved immediate postoperative pain control after haemorrhoidectomy, but only for up to 6 hrs.^[9] These findings are comparable to our study. In our study, the addition of dexmedetomidine to ropivacaine resulted in early onset of action 8.16 ± 2.5 mins. compared to ropivacaine alone, that is 13.6 ± 4.1 mins. The average of first request for rescue analgesia is 312.2 ± 16.1 mins. in Group 1 and 156.2 ± 12.7 mins. shows longer post-operative analgesia produced by dexmedetomidine.

Memis et al reported that the addition of $0.5 \mu\text{g/kg}$ dexmedetomidine to lidocaine for intravenous regional anaesthesia shortened sensory and motor block onset times and prolonged sensory and motor block recovery times without causing side effects.^[10]

Coskuner et al previously demonstrated that intravenous administration of dexmedetomidine might prolong the recovery time of the sensory blockade of bupivacaine-induced sensorial blockade during epidural anaesthesia.

Kaya et al previously demonstrated that the intravenous administration of dexmedetomidine prolonged spinal bupivacaine sensory blockade and provided additional analgesia.^[11]

However, there are currently no clinical data regarding the effects of additional local infiltration of dexmedetomidine in lumbar spine surgery.

Although, this study showed that additional local infiltrations of dexmedetomidine could improve postoperative pain, thus reducing the need for analgesic, the underlying mechanism of this effect remains unclear.

Supraspinal analgesic secondary to absorption to systemic circulation, potentiating the blockade of C-fibres or augmenting the effects of local anaesthetics, vasoconstriction action and preventing norepinephrine release of dexmedetomidine are suggested to be involved in this mechanism.^[12,13]

CONCLUSION

It was concluded that both Group D and control group mixture provides adequate post-operative analgesia with minimum side effects. While dexmedetomidine when used as an adjuvant to ropivacaine prolongs the duration of post-operative analgesia and produces good sedation.

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