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EFFECTS OF ADDING DEXMEDETOMIDINE TO 0.75% ROPIVACAINE IN PATIENTS UNDER-GOING ELECTIVE LOWER LIMB ORTHOPEDIC PROCEDURES UNDER EPIDURAL ANAESTHESIA.

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ABSTRACT

Background Epidural block not only provides surgical anaesthesia but post-operative analgesia also in patients undergoing lower limb orthopedic surgeries. Ropivacaine, is safe and effective drug for regional anaesthetic techniques and adding adjuvant Dexmedetomidine which is alpha-2 agonist is reported to have synergistic effect for epidural anesthesia. The aim of our study is to evaluate the efficacy and safety of dexmedetomidine as an adjuvant to epidural 0.75% ropivacaine in patients undergoing lower limb orthopaedic surgeries.

Method 40 adult patients,18 -70 yr of age, of both sex, of ASA grade I/II undergoing lower limb orthopaedic surgeries were enrolled for this study. Patients were randomised in two groups of 20 patients each: Group C receiving epidural ropivacaine only whereas Group D receiving epidural ropivacaine and dexmedetomidine. Patients of group C received 20 ml 0.75% ropivacaine and group D received 20 ml 0.75% ropivacaine + 1 µ kg-1 dexmedetomidine epidurally. Various characterstics like sensory onset time, time to complete motor block, duration of sensory,analgesia and sedation scores, hemodynamic changes and any side effect were recorded and statistically analysed was done. The p value<0.05 is considered significant and p<0.001 as highly significant.

Results The demographic profile of patients was comparable in both the groups. Onset of sensory block and establishment of complete motor blockade was significantly earlier in the ropivacaine with dexmedetomidine group. Postoperative analgesia was prolonged significantly in the ropivacaine with group. Sedation scores were also higher in the dexmedetomidine group with statistically highly significant difference (p<0.001).

Conclusion Dexmedetomidine as an adjuvant is effective with ropivacaine for epidural block as it prolongs duration of motor block as well as analgesia with adequate sedation and minimal side effects.

KEYWORDS : dexmedetomidine, Ropivacaine, epidural anaesthesia, lower limb orthopedic procedures,adjuvant

INTRODUCTION :

Peripheral nerve block is one of the common regional anaesthetic technique and is used for a broad spectrum of procedures like surgical, interventional, or diagnostic. Long-acting blocks along with local anaesthetics (LAs) such as ropivacaine or bupivacaine are beneficial for improved postoperative pain, but the duration of sensory block is still not sufficient to avoid the postoperative usage of opioids.. Neuraxial blocks for orthopedic surgery has increased rapidly from the last few decades, with increasing demand for post-operative pain relief and also to decrease the need for intravenous anaesthetic drugs during the post-operative period. Various adjuvants are being used with local anaesthetics to prolong the duration of intra operative and post-operative analgesia.[1] The α_2 adrenergic agonists have both analgesic and sedative properties when used as an adjuvant in regional anesthesia.[2] Dexmedeto midine, a newer and highly selective α_2 adrenergic agonist has evolved as a panacea for various applications and procedures in the peri-operative and critical care settings.[3] Advantages of being hemodynamically stable and to decreased oxygen demand makes it a useful adjuvant.[4] Dexmedetomidine is an agonist of α_2 adrenergic receptor –agonist(FIG 1).

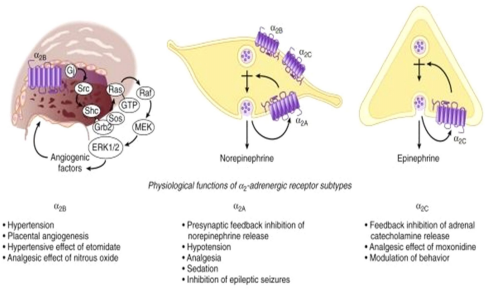

Fig 1. Showing physiological functions of alpha-2 adrenergic receptor.

After epidural administration of Dexmedetomidine, it is rapidly detected in CSF within five mins,however only 22% is absorbed into intra thecal space. Based on earlier studies, it was found that Dexmedetomidine produces prolonged post-operative analgesia with minimal side-effects when added to Ropivacaine in epidural and caudal anaesthesia.[5,6,7,8] Since only few studies are available where Dexmedetomidine's efficacy as an adjuvant to Ropivacaine in epidural anesthesia had been explored,[6,7,8] so we planned a prospective double blind study to explore the efficacy of Dexmedetomidine as an adjuvant to Ropivacaine in terms of various parameters in epidural anaesthesia for lower limb surgeries.

MATERIALS AND METHODS

In a prospective, randomized double blind study, 40 patients of American Society of Anaesthesiologist (ASA) physical status I and II in the age group [18-70] years of either sex, planned to undergo lower limb orthopedic surgeries under epidural anaesthesia were included after approval from the institution's ethical and scientific committee as well as after taking informed consent from patient as well. Patients with pregnancy, coagulation or neurological disorders, deformity or previous surgery of spine, morbid obesity, anticipated difficulty in regional anaesthesia, allergy to the study drug and unwillingness were excluded from the study. Patients were randomly divided into two group of 20 patients each,by a computer generated table of random numbers by a person blinded to the procedure, as Group C (n = 20) and Group D (n = 20). A day before surgery, a detailed pre anaesthetic check-up was done. Patients were asked to keep nil by mouth by restricting fluids and solids for at least 6 hrs before the operation. Interpretation of visual linear analogue scale (VAS) was explained to determine the level of analgesia in the post-operative period. All patients were given tablet alprazolam 0.25 mg on a night before surgery. On the day of surgery, injection glycopyrrolate 0.2 mg was given by intramuscular route 45 min before the operation and injection midazolam 0.04 mg/kg body weight by the intravenous route just before the procedure started.

Pre-operatively vitals like pulse rate, non-invasive systolic and diastolic blood pressure (DBP) and respiratory rate was recorded. In

the operation room, a good intravenous access was secured and patients were preloaded with 10 ml/kg body weight of Ringer Lactate solution over 15-20 min. Multipara monitor was attached to the patient and baseline pulse rate, non-invasive systolic blood pressure (SBP) and DBP, oxygen saturation, and electrocardiogram (ECG) were recorded. The study drug was prepared by an anaesthesiologist who then handed it to another anaesthesiologist blinded to the nature of the drug given to him/her. Patients were put in the lateral decubitus position and under all aseptic precautions, Epidural block was performed through midline approach in L3-L4 inter-vertebral space. Skin wheal was raised with 2% inj lignocaine and lumber epidural space was identified with an 18G Tuohy needle using loss of resistance technique. Then test dose of 2-3 ml of lignocaine with epinephrine 1:200,000 after negative aspiration for blood and CSF was given to rule out accidental intra-vascular or intra-thecal injection then the study drug was given slowly in the desired epidural space. Group C (n = 20) received 20 ml of 0.75% ropivacaine hydrochloride and Group D (n = 20) received 20 ml of 0.75% ropivacaine hydrochloride plus dexmedetomidine (1 µg/kg bodyweight). Volume of the drug was kept constant as 22 ml in both the groups by adding normal saline to avoid biasness during drug administration. Position of the patients were turned supine immediately after epidural block. 100% Oxygen was administered to all the patients @ 6 L/min. Continuous monitoring of pulse rate, respiratory rate, non-invasive SBP and DBP, SpO2 and ECG was done. Readings were recorded pre-operatively, and then intra-operatively every 5 min for the first 30 min and thereafter every 15 min till the end of surgery. Bradycardia was treated with intravenous Atropine 0.6 mg, hypotension was treated with additional fluid like Ringer's lactate solution intravenously or if needed injection mephentamine 6 mg titrated according to blood pressure.

Sensory block

Sensory block was assessed by loss of sensation to pin prick in the midline using a 22 gauge blunt hypodermic needle every 2 min interval until T10 dermatome was reached and then every 5 min interval until no change in level occurred. Onset of sensory block to T_{10} dermatome level, maximum level of sensory block achieved, time taken to achieve maximum sensory level and duration of sensory block (interval from epidural administration of drug until the regression of sensory block to S_1 dermatome) was noted.

Motor block

The degree of motor block was assessed every 5 min for first 30 min and then every 15 min till completion of surgery by the modified Bromage score. Bromage 0: Patient is able to move hip, knee and ankle. Bromage 1: Inability to move the hip but is able to move knee and ankle, Bromage 2: Inability to move hip and knee but can move ankle, Bromage 3: No movement at all and unable to move hip, knee and ankle. Maximum motor block achieved, time required to reach maximum motor block and total duration of motor block (motor recovery to Bromage 0) was noted.

All durations were calculated considering the time of epidural injection as zero. Analgesia was monitored by using VAS score. VAS score was recorded 5 min before epidural, at the start of surgery and then every 15 min interval till the surgery was over. Postoperatively, VAS was recorded half hourly for first 1 h then one hourly for 12 h and then three hourly for next 12 h till 24 h(FIG.2)

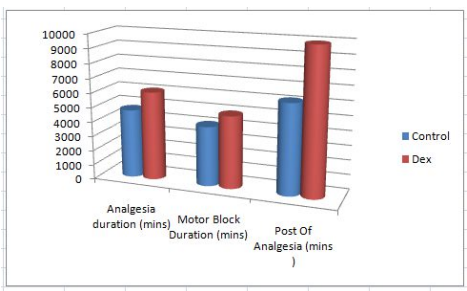

FIG 2 : LEVELS OF ANALGESIA AT DIFFERENT STAGES

When patients had VAS score of more than 3, rescue analgesia in the form of injection tramadol 50 mg slow intravenously was given. Time to first dose of rescue analgesia, number of doses of rescue analgesia and the time at which it was repeated was recorded in both groups. The time at which patient demanded first dose of rescue analgesia was the primary end point of this study because at this time the effect of epidural block had weaned off.

The operation was started on achieving adequate sensory block at T8 dermatome. In case of failed epidural block, procedure was converted to general anaesthesia and these patients were excluded from the study. The quality of surgical analgesia was assessed and graded as: Excellent if no supplementary drugs were required, good if only one analgesic was required, fair if more than one analgesic was required and poor if general anaesthesia was required. Following sedation score was used. 0 as no sedation,

1. Patient somnolent but responding to verbal commands,
2. Patient somnolent, not responding to verbal commands but responding to manual stimulation and
3. Patient somnolent, not responding to verbal commands and manual stimulation.

After completion of surgery, patients were monitored for sensory and motor block, post-operative analgesia (VAS score), hemody namic parameters, side effects and complications for 24 h post-operatively. Any side effect or complication like hypotension, bradycardia, headache, dry mouth, nausea and vomiting, local anesthetic toxicity, backache, urinary retention and sedation were noted in these 24 h.

Statistical analysis

Statistical analysis was done by SPSS version 15.0 for analysing the collected data. As there was no prior historic evidence available, the sample size was kept to be large enough (n>30) for statistical purposes as per the Central Limit Theorem. Parametric data were reported as arithmetic mean±standard deviation and analysed by using student t-test. The comparison was studied using chi-squared test or the Fisher's exact test as appropriate, with the P value reported at the 95% confidence interval. P<0.05 was considered statistically significant.

RESULTS

The groups were comparable with respect to age, height, weight and ASA physical status. There was no significant difference in the type and duration of surgery [Table 1 and fig 3].

VARIABLES		CONTROL	DEX
Age		42.25	39.10
Sex	Female	3	4
	Male	17	16
Height (cm)		169.35	163.15
Weight (kg)		69.95	66.75
Level Of Epidural	L1-L2	2	2
	L2-L3	10	10
	L3-L4	8	8
Cathetar Length (cm)		6.5	6.85
Surgery	IM / IL Nailing	10	9
	Illizarao ring fixation	4	2
	DHS	2	5
	TKR	1	1
	THR	1	0
	DCS	0	1
	Encirclage / TBW L Patella	1	0
	Plate & Screw fixation	0	2
	Hemiarthroplasty	1	0
ASA	I	12	15
	II	8	5
DURATION OF SURGERY (mins)		158.25	177

Table 1. the type and duration of surgery

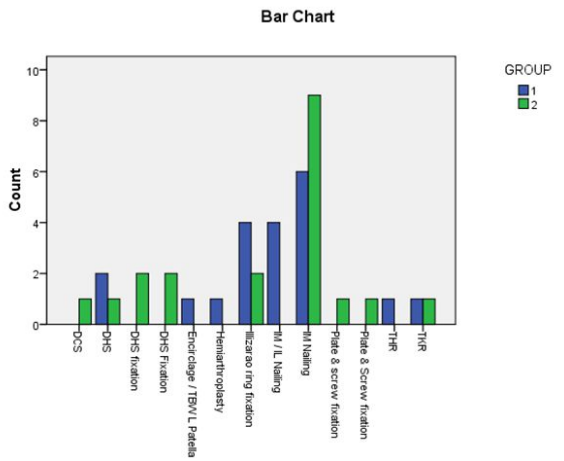

Fig 3.DISTRIBUTION OF SURGERY

The results regarding the characteristics of sensory block and motor block are summarised in [fig 4, table 2].

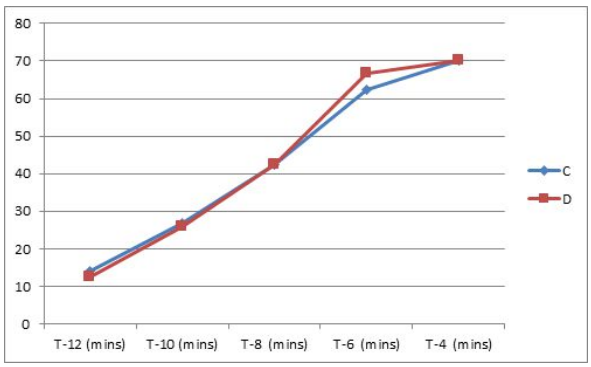

Fig 4. characteristics of sensory block

VARIABLES	CONTROL	DEX	'P' VALUE
Block Onset Time (T-12)mins	13.90	12.45	0.085
Duration Of Analgesia (mins)	236.35	304.25	0.021
Regression Time	115.55	177.30	0.051
Motor Block Duration (mins)	204.65	248.00	0.042
Post Of Analgesia (mins)	309	496.95	0.001

Table 2. characteristics of sensory block and motor block

There was no difference between group D and R in the highest level of block (T5 and T6, respectively) or in the time to reach peak level (11.65±1.73 and 12.05±1.64 minutes, respectively). Block regression was significantly slower with the addition of intrathecal dexmedetomidine as compared to ropivacaine alone, as both time to two segment regressions and time to S2 regression were significantly more with intrathecal dexmedetomidine. On statistical analysis, the maximum VAS score in the group D was lower as compared to group R up to 24 hours postoperatively [fig5].

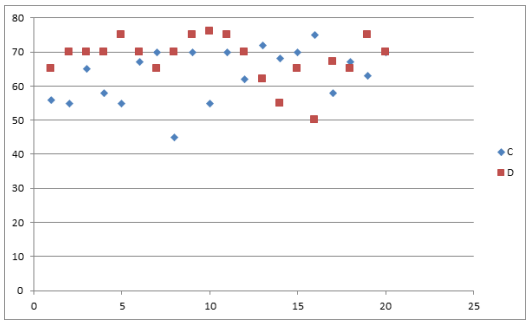

Fig 5 : Comparison of both groups in respect to Level Of Analgesia

The duration of analgesia was significantly prolonged with the addition of dexmedetomidine as compared to ropivacaine alone (478.4±20.9 min and 241.67±21.67 min, respectively). There was no serious complication in the 40 study patients, like nausea, vomiting, shivering, itching, pruritus, sedation, respiratory depression and hypotension.

DISCUSSION

The results of the present study show that supplementation of epidural Ropivacaine with Dexmedetomidine significantly prolongs the duration of sensory and motor block with improved quality of postoperative analgesia as compared to Ropivacaine alone. The mechanism by which α_2 adrenergic agonists prolong the motor and sensory block of local anesthetics may be an additive or synergistic effect secondary to the different mechanisms of action of local anesthetics. Dexmedetomidine act by binding to the presynaptic C-fibers and post synaptic dorsal horn neurons. They produce analgesia by depressing the release of C-fiber transmitters and by hyperpolarisation of post synaptic dorsal horn neurons.[9,10,11] The complimentary action of local anesthetics and α_2 adrenergic agonists accounts for their profound analgesic properties. The prolongation of motor block may be the result of binding α_2 adrenergic agonists to the motor neurons in the dorsal horn.[9,10] The use of Dexmedetomidine has been studied as an epidural adjuvant by various authors who have observed its synergism with local anesthetics without any additional morbidity.[6,7] Clinical studies exhibit potentiation of neuroaxial local anesthetics, decrease in intraoperative awareness and anesthetic requirements and postoperative analgesia when epidural or caudal dexmedetomi dine was used in conjunction with general anesthesia.[12,13,14]

CONCLUSION

It was concluded that anesthesia in both the groups was effective and patients were hemodynamically stable. However dexmedeto midine group was better as regards to prolonged duration of sensory block, postoperative analgesia with reduced doses of rescue analgesic required and better patient satisfaction score. However, prolonged duration of motor block and sedation produced with Dexmedetomidine may be undesirable for short surgical procedures or ambulatory surgery. DEX has significant synergistic interaction with epidural Ropivacaine in

- Prolonging duration of analgesia($p<0.02$)
- Prolonging duration motor block($p<0.04$)
- Post-op duration of analgesia($p<0.001$)

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Conflict of Interest: None declared.

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