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A COMPARATIVE STUDY OF EFFECT OF INTRAVENOUS DEXMEDETOMIDINE VS. PLACEBO BEFORE BRACHIAL PLEXUS BLOCK ON PATIENT SATISFACTION AND SUCCESS OF BLOCK

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ABSTRACT: The brachial plexus block(BPB) has gained importance as regional anaesthetic technique for upper limb surgery. The primary aim of our study was to evaluate the addition of intravenous dexmedetomidine before BPB on overall patient satisfaction and sucess with objective of comparing the onset and duration of block, haemodynamic stability and sedation score. A randomized double blind prospective study was carried out on seventy patients of ASA grade I to III of either sex aged between 18 – 65 years scheduled for upper limb orthopaedic surgeries under BPB Who were randomly allocated into two groups: Group D (Dexmedetomedine) received Inj dexmedetomidine 1 µg/kg in intravenous 100 ml saline and Group P (Placebo) received intravenous 100 ml saline started 10 min before block. Onset and duration of block, quality of block, Haemodynamic variables, time to first rescue analgesics in post-op period, Sedation score, VAS score and Incidence of side effects and complications were recorded. Statistical analysis was done using Graph pad software. Hemodynamic variables, sedation score and satisfaction scores were analyzed by z-test, while qualitative data were analyzed by Chi-square test. **Result:** Mean Sedation score was significantly higher in group D while mean pulse rate and mean arterial pressure were significantly lower in group D than group P. The Quality of block was significantly higher(p=0.0314) in group D (88.57%) than group P(80%). Overall Patient satisfaction was higher(p=0.0008) in group D than group P. **Conclusion:** The addition of dexmedetomidine as a premedication before BPB improves patient satisfaction, with stable hemodynamics, high quality of block and comfortable sedation without any significant side effect.

INTRODUCTION: Halsted and Hall first described the technique of brachial plexus block for upper limb surgeries in 1885 [1]. Since then a variety of modifications in the technique has been described and in recent years, the technique has gained importance as regional anesthetic technique for surgical, diagnostic and therapeutic purposes in interventional pain management. It provides ideal operating conditions by producing complete muscular relaxation, maintaining stable intraoperative hemodynamic, and the associated sympathetic block.

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Various adjuvant drugs like opioids [2], clonidine [3] and neostigmine [4] have been evaluated in conjunction with local anesthetics to prolong the period of analgesia but all of these drugs are used off label and none are approved by FDA for administration through this route.

There are no studies to our knowledge in the literature studying the effect of intravenous dexmedetomidine sedation on patient satisfaction and success of brachial block. So, we studied effect of intravenous dexmedetomidine on patient recall and acceptability of anesthesia procedure. Dexmedetomidine is a highly selective α_2 agonist which has a set of unique effects that include titratable sedation, sympatholysis, and analgesia without significant respiratory depression. In this study, we also compared the onset and duration of brachial plexus block (BPB), the time at which the patient first feels pain after performing BPB, the

need for use of analgesics, and the rate of complications with single dose intravenous dexmedetomidine to a control group, who were only infused with normal saline.

MATERIALS AND METHODS:

This randomized double blind prospective study was conducted in 2013-2015 after approval by ethical committee. Seventy patients in the age group of 18 – 65 years of ASA grade I to III scheduled for upper limb orthopedic surgeries under brachial plexus block were included in the study after obtaining written informed consent. Patients with CNS disorder and preop neurological deficits, known hypersensitivity to local anesthetic drugs, bleeding disorders, uncontrolled diabetes mellitus, renal and liver diseases, patient refusal, circulatory instability, pregnant women, patients with epilepsy and peptic disease were excluded. All patients underwent a thorough pre-anaesthetic check up including routine investigations and taught about pain scale regarding VAS scale during pre operative visit.

After securing an intravenous line, pulse oxymeter, non invasive blood pressure cuff and ECG electrodes were applied and baseline pulse rate, blood pressure and respiratory rate, sedation scores and pain score were recorded. Patients were randomly (computer generated randomization) divided into two groups :Group P (Placebo) received intravenous 100 ml saline started 10 min before block and Group D (Dexmedetomedine) received Inj dexmedetomidine 1 µg/kg in intravenous 100 ml saline started 10 min before block.

After that, patients were taken inside the operation theatre, monitors were applied and all patients were premedicated with Inj. Glycopyrrolate 0.2mg intravenously, Inj. Ondansatron 4mg intravenously and Inj. Ranitidine 50 mg intravenously. Brachial plexus block was given by supraclavicular or parascalene approach and 35ml of drug mixture consisting of Inj. Lignocaine+adrenaline(2%) 14cc, Inj. Bupivacaine (0.5%) 15cc and Inj. Normal saline 6cc = 35cc was given after careful negative aspiration.

Motor block was assessed by modified bromage scale while sensory block was assessed by pin prick, C_5 to T_1 dermatome at 0min, 1min, 2min, 3min, 4min, 5min, 6min, 8min till 15 minutes after completion of drug injection and sedation score is assessed by ramsay sedation score (evaluated at every 15 minutes). Pulse rate, blood pressure, SpO_2, sedation and duration of sensory and motor blockage were monitored intra-operatively and post-operatively.

Patients were examined for duration of analgesia as per Visual Analogue Scale (VAS) which was recorded post operatively at every 4 hours till VAS score of ≥ 4, when first demand for analgesia was given in the form of Inj. Diclofenac sodium 75 mg IM and time of rescue analgesia was noted. Any incidence of side effects and complications like nausea, vomiting, pneumothorax, hematoma, local anaesthetic toxicity, bradycardia, hypotension and post block neuropathy in the intra and post-operative period were noted.

Power of study is 80% and differences are considered statistically significant at $P < 0.05$. Quantitative data e.g., intraoperative hemodynamic variables (heart rate, systolic blood pressure, oxygen saturation), onset and duration of sensory and motor block between the groups, sedation scores, pain scores and satisfaction scores were compared using z-test, while qualitative data e.g., demographic variables, success rates, rescue analgesic requirements in both groups were compared by chi-square test. Statistical analysis was done using Graph pad software.

RESULTS AND DISCUSSION:

Our study shows that demographic data were comparable in both groups.

Although the time for onset of sensory block was faster and duration of sensory block was longer in group D compared with group P but differences were statistically insignificant while the time for onset of motor block was faster and duration was longer in group D compared to group P but data were statistically not significant.

TABLE 1: CHARACTERISTICS OF SENSORY AND MOTOR BLOCKADE

Sensory blockade		Group D (Mean±SD)	Group P (Mean±SD)	Z value	P-value	Significance
	Onset (in mins)	7.2±3.52	8.37±4.47	-1.2180	0.223191	Not significant
	Duration (in mins)	283.14±33.64	276±50. 64	0.6643	0.5065	Not significant
Motor Blockade	Onset (in mins)	13.11±3.03	13.54±3.89	-0.514	0.607	Not significant
	Duration (in mins)	213.57±33.73	211.71±43.33	0.20008	0.841	Not significant

TABLE 2: QUALITY AND SUCCESS RATE OF BLOCK

Quality of block	Group D	Group P	Chi square statistic	p-value	Significance
Adequate	32 (91.43%)	25 (71.43%)	4.63	0.0314	
Inadequate	3 (8.57%)	10 (28.57)			Significant
Failed	13 (27.08%)	18 (33.96%)	0.5603	0.4541	Not significant

The quality of block was higher in group D (88.57%) compared to group P (72.92%) which was statistically significant (p value- 0.0314) while the success rate between the two groups came out to be statistically insignificant.

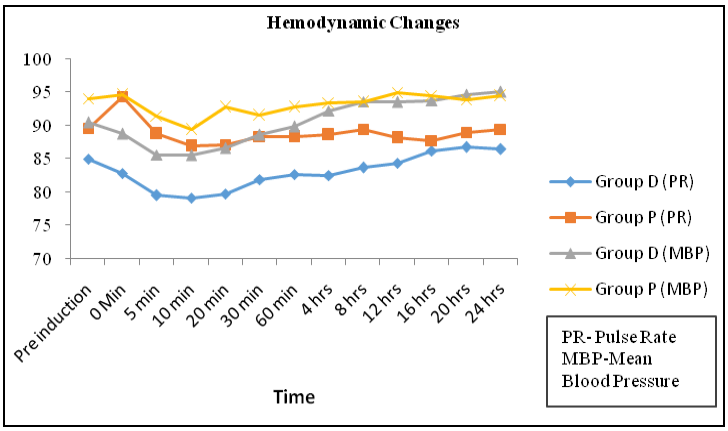

FIG.1: HEMODYNAMIC CHANGES

Mean pulse rate in group D was lower compared to group P from the time immediately after induction upto 8 hrs after induction, Who were statistically significant (p value <0.05) and mean blood pressure in group D was lower compared to group P since immediately after induction upto 20 minutes after induction, Who were statistically significant (p value <0.05).

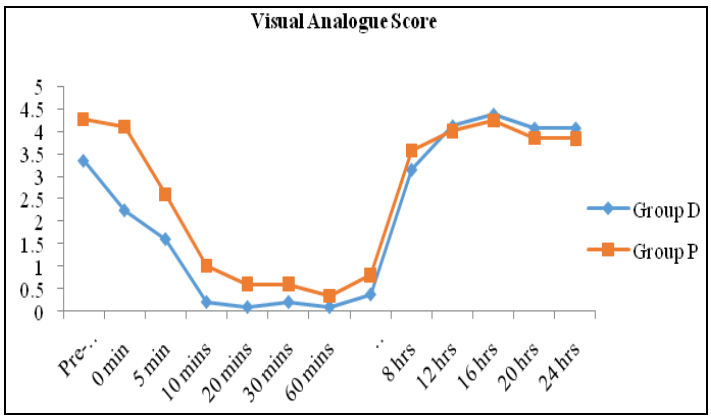

FIG.2: MEAN VISUAL ANALOGUE SCORE

Mean Visual analogue score in group D was lower compared to group P right from the time before induction upto 30 minutes after induction, which were statistically significant.

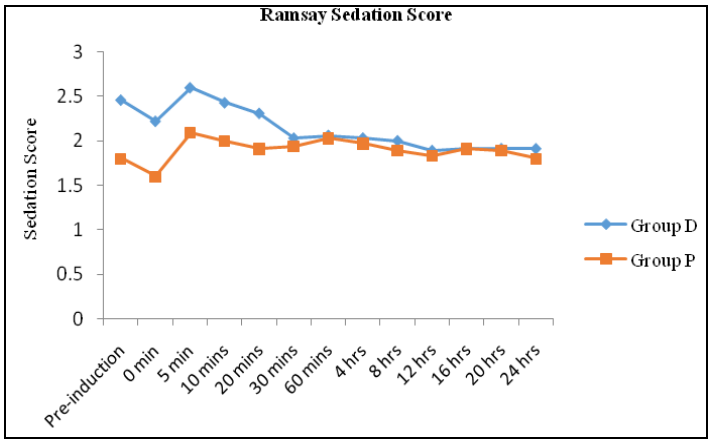

FIG.3: MEAN SEDATION SCORES

Mean Sedation score in group D was higher compared to group P right from the time before induction upto 20 minutes after induction, which were statistically significant (p value<0.05). The mean time of duration of analgesia in group D was longer compared to group P but it was statistically insignificant.

TABLE 3: PATIENT SATISFACTION

Patient satisfaction (according to Cohen et al)	Group D	Group P
5.Very satisfied	13	4
4.Satisfied	12	14
3.Somewhat satisfied	4	16
2.Not satisfied	1	1
1.Very unsatisfied	0	0
TOTAL	35	35
Mean Satisfaction score	4.2±0.58	3.6±0.55

The mean patient satisfaction score in group D was higher (4.2±0.58) compared to group P (3.6±0.55) and was statistically significant (p=0.0008). There were no any side effects observed in both the groups.

Brachial plexus block is a versatile and reliable regional anaesthesia technique and suitable alternative to general anaesthesia for upper limb surgery that is often used to provide not only anaesthesia but also postoperative analgesia after surgery.The technique is performed with local anesthetics like lignocaine and bupivacaine.

The procedure of giving brachial block is painful and unpleasant for the patient. Dexmedetomidine is a highly selective alpha-2 adrenoreceptor agonist with α_2:α_1 binding ratio of 1620:1 compared to 220:1 for Clonidine. Dexmedetomidine has analgesic and sedative effect without causing respiratory depression. Dexmedetomidine has been used as an adjuvant during regional and local anesthesia in several studies [5].

In this study, we compared single dose intravenous dexmedetomidine, to a control group, who were only infused with normal saline for the onset and duration of brachial plexus block (BPB), the time at which the patient first feels pain after performing BPB, the need for use of analgesics, and the rate of complications.

Dexmedetomidine has been used intravenously in doses ranging from 0.1 to 10 µg/kg/h but higher doses have been associated with a significant incidence of bradycardia and hypotension. Jia Song et al [6] concluded that intravenous injection of dexmedetomidine 1 µg/kg followed by continuous infusion produced adequate levels of sedation. After observing various studies done by Rutkowsa Et al [7], Park JW et al [8] and others on intravenous dexmedetomidine sedation before brachial plexus block, we selected a dose of 1µg/kg as premedication in our study. As rapid administration of dexmedetomidine might produce tachycardia, bradycardia and hypotension, we administered dexmedetomidine, 1µg/kg slowly, over a period of 10 min in our study.

Velayudha Sidda Reddy et al [9] evaluated the efficacy of intravenous dexmedetomidine

premedication with clonidine and placebo in spinal anaesthesia and observed that heart rates in the dexmedetomidine group appears to be lower than that of clonidine and placebo groups, but there is no statistically significant difference among the groups except at 5 mins after spinal anesthesia where the mean heart rate was significantly lower (*P* = 0.0299). This study is in contrast to our study where mean pulse rate in group D was lower compared to group P from the time immediately after induction upto 8 hrs after induction, which were statistically significant probably because the decrease in the heart rate in dexmedetomidine group in this study might have been masked by the sympathetic blockade caused by spinal anaesthesia.

Study done by Rabab Saber Saleh Elsayed Mahrous [10] on effect of dexmedetomidine in reducing haemodynamic response to general anesthesia showed patient in dexmedetomidine group (0.4µg/kg/hr) had statistically significant lower mean arterial blood pressure compared to fentanyl group(1 µg/kg) till 5 minutes after surgery. Our results were comparable to this study where change in mean arterial pressure was statistically significant (p=0.001) till 5 minutes postsurgery which differs from our study in that the difference was significant till 20 minutes after induction with brachial block, probably because we used only loading dose of intravenous dexmedetomedine (1µg/kg) in contrast to this study where they kept continuous infusion of maintenance dose(0.4µg/kg/hr).

In our study , we found that Mean sedation score in dexmedetomidine group was significantly higher compared to placebo group right from the time before induction of brachial plexus block up to 20 minutes after induction, which was comparable with study done by Mizrak A et al [11] who observed that premedication with a single dose dexmedetomidine 0.5 µg/kg before IVRA caused increase in intraoperative and postoperative RSS scores at 5,10,30,60 and 120 minutes (p<0.001) compared with placebo group.

Prerana Shah et al [12] compared postoperative ICU sedation between dexmedetomidine and propofol and found out that the mean RSS was between 2-4 and 2-3 for dexmedetomidine and propofol groups respectively, which was statiscally not significant in contrast to our results probably because we had compared dexmedetomidine with placebo instead of propofol, which has enough sedative properties.

Jia Song et al [6] studied dexmedetomidine for sedation of patients undergoing elective surgery under regional anesthesia (spinal anesthesia) and observed that RSS score was increased significantly after 20 minutes of injection of dexmedetomidine till patient was shifted to PACU(Post anesthesia care unit) compared to the baseline sedation score. But in contrast to this study we had compared dexmedetomidine with placebo group instead of baseline findings.

Mi Hyeon Lee et al[13] also studied effects of intravenous dexmedetomidine at different doses(0.5 and 1.0 µg/kg) with placebo on spinal anesthesia and concluded that dexmedetomidine significantly raised the duration of sensory block(D-0.5 group 86.5±24.3,p=0.001; D-1 group 92.5±30.7,p=0.0001; control group 57.6±23.2) motor block (D-0.5 group 132.9±43.4,p=0.0152; D-1 group 130.4±50.4,p=0.024; control group 98.8±34.1). All the results are different from our study in that duration of block was statistically not significant in our group probably because all of the studies involved initial loading dose followed by maintenance dose of dexmedetomidine, whereas our study involved only initial loading dose.

In our study, the onset of sensory and motor block was faster and duration of sensory and motor block was longer in patients who received dexmedetomidine before brachial block than the placebo group respectively although it was not statistically significant but Rutkowska et al [7] showed results which were in contrast to our results where the motor and sensory block was longer in the dexmedetomidine group, which was statistically significant (11.9 +/- 3.8 vs. 9.4 +/- 3.4 h, P = 0.0085 and 9.4 +/- 3.4 vs. 7.3 +/- 2.8 h, P = 0.030, respectively). Study done by Park JW et al [8] also showed that the motor and sensory block duration , and the time at which the patient feels pain after brachial block were longer in Dexmedetomidine group compared to control group.

In our study, Mean Visual analogue score in group D was significantly lower compared to group P

right from the time before induction up to 30 minutes after induction. Studies done by Mirzak A et al [11] also revealed that premedication with Dexmedetomidine (0.5µg/kg) reduced intraoperative and postoperative VAS scores compared with placebo group. Unlike our study, which didn't have significant changes in mean VAS scores in the postoperative period this study reduced both intraoperative and postoperative VAS scores, probably because the duration of IVRA might be of short interval making the duration of action of dexmedetomidine extend up to the postoperative period. The duration of brachial block usually lasts for a longer period masking the analgesic effect of dexmedetomidine and thus making postoperative analgesia of bolus dose of dexmedetomidine insignificant.

Eun-Jin Moon et al [14] compared monitored anaestesia care (MAC) with dexmedetomidine (1 µg/kg) and intermittent ketamine with spinal anaesthesia(SA) for patient satisfaction using ISAS scale{Iowa satisfaction with anaesthesia scale. The verbal rating scale 0(worst) to 10(best)} and concluded that patient's(p=0.018) and surgeon's satisfaction(p=0.001) were lower in MAC group (7.4 and 6.2 respectively) compared to SA group (9.0 and 9.1 respectively). This is in contrast to our results probably because spinal anaesthesia provided complete analgesia as well as relaxation which is far superior in quality to intermittent doses of ketamine and dexmedetomidine infusion. Moreover SA provided postoperative analgesia as well to greatly improve the patient's satisfaction.

Study done by Ashraf Ghali et al [15] regarding sedation with dexmedetomidine (0.4µg/kg/hr after loading dose of 1 µg/kg over 10 minutes) and propofol (0.5-2mg/kg/hr after loading dose of 0.7mg/kg) observed that the surgeon's satisfaction with patient's sedation was similar for both groups. While, in the dexmedetomidine group, there was higher patient's satisfaction compared with the propofol group.

CONCLUSION: From our study, we found that, the addition of dexmedetomidine as a premedication before brachial plexus block provides stable pulse rate without any significant bradycardia, stable mean arterial pressure, comfortable sedation without any need for airway assistance, higher quality of block and high success rate with higher patient's satisfaction without any difference in the duration of analgesia with single dose of intravenous dexmedetomidine.

So we conclude that addition of dexmedetomidine before brachial plexus block improves patient satisfaction without any significant side effects.

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