The Effect of Dexmedetomidine versus Fentanyl as an Adjuvant to Bupivacaine in Ultrasound Guided Infraclavicular Brachial Plexus Block. Comparative Clinical Study.

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Abstract: **Background:** Surgical anesthesia of the upper limb, from the elbow to the hand, may be readily achieved by injection of local anesthetic around the brachial plexus. This regional anesthesia technique avoids the need for a general anesthetic and its accompanying risks. Control of postoperative pain is also excellent as the sensory block typically persists for several hours following injection. The use of ultrasound appears to permit accurate deposition of the local anesthetic perineurally, and has the potential to improve the success and decrease the complications of infraclavicular brachial plexus block. α2-adrenergic (α2-AR) receptor agonists have been successfully used in several clinical settings in view of diverse actions which include sedation, analgesia, anxiolysis, perioperative sympatholysis, cardiovascular stabilizing effects, reduced anesthetic requirements, and preservation of respiratory function. Dexmedetomidine, is a selective α2-adrenoceptor agonist that is used as an adjuvant mixed with local anesthetics during regional anesthesia. Addition of opioids to local anesthetics has gained popularity. Opioids have multiple central neuraxial and peripheral mechanisms of analgesic action Fentanyl is a mu opioid receptor agonist that has been used as adjuvant to local anesthetics to improve efficacy of peripheral nerve block. **Methods:** sixty patients of ASA I and II scheduled for Below mid humerus elective surgeries not more than two hours were randomly allocated into three groups. After premedication by Atropin Sulphate (1 mg/ml) (dose:,02 mg/kg) and Medazolam (5 mg/ml) (dose:,015-,03 mg/kg) Patients will be randomly allocated into one of three groups every group contain twenty patient C group (control group): Twenty patients received ultrasound-guided infraclavicular brachial plexus block with 20 volume mixture of 18 ml bupivacaine 0.5% + 2 ml normal saline 0.9% D group (dexmedetomidine group): Twenty patients received ultrasound-guided infraclavicular brachial plexus block with 20 volume mixture of 18 ml bupivacaine 0.5% + 100 ugdexmedetomidine in 2 ml F group (fentanyl group): Twenty patients received ultrasound-guided infraclavicular brachial plexus block with 20 volume mixture of 18 ml bupivacaine 0.5% + 100ug fentanyl in 2 ml The total volume of the local anesthetic mixture was equal (20 ml) for all patients. sensory block, Motor block, duration of sensory and motor block, complication, post-operative pain, analgesia request, and hemodynamic changes were assessed A comparison was made between the three groups as regards motor and sensory block, duration and quality of postoperative analgesia, hemodynamic and respiratory variables as well as side effects during forearm or hand surgery under ultrasound guided Infraclavicular block. Demographic data (age, sex, BMI) and operational data (duration of surgery) were statistically comparable among the three groups. **Results:** The present research revealed that infraclavicular brachial plexus block with 20ml 0.5% bupivacaine supplemented with 100µg dexmedetomidine significantly affect Block characteristics evident by shortened onset time of both sensory and motor block compared with the same block supplemented by 100µg fentanyl and 0.5% bupivacaine in patients undergoing upper limb surgery. Also addition of dexmedetomidine significantly prolong time to complete sensory resolution and regression of motor block with prolonged analgesic effects of infarclavicular block evident by decreased postoperative pain scores (VAS), total analgesic consumption and prolongation of time to first request for analgesia. No side effects requiring any intervention were noticed in either group. No patients in the study demonstrated any signs or symptoms of local anesthetic drug toxicity. There were no serious postoperative complications in the three groups. Ultrasound guided Infraclavicular block appears to be associated with a high success rate, short onset time, low complication rate and excellent analgesia even when a tourniquet was used. It was well tolerated by patients. **Conclusion:** We conclude that the addition of dexmedetomidine or fentanyl to local anesthetic mixture in infraclavicular brachial plexus block hastens the onset and prolong the duration of sensory and motor blocks, as well as the duration of postoperative analgesia. Also the use of ultrasound appears to permit accurate deposition of the local anesthetic perineurally, and has the potential to improve the success and decrease the complications of infraclavicular brachial plexus block.

[Ahmed Mohammed Saad Mustafa Elsarag, Anwar Mohammed Mostafa Alhassanin and Saad Eldin Mahmoud Abdelrahman Elkateeb. **The Effect of Dexmedetomidine versus Fentanyl as an Adjuvant to Bupivacaine in Ultrasound Guided Infraclavicular Brachial Plexus Block. Comparative Clinical Study..** *Nat Sci* 2017;15(11):103-113]. ISSN 1545-0740 (print); ISSN 2375-7167 (online). http://www.sciencepub.net/nature. 13. doi:10.7537/marsnsj151117.13.

Keywords: Dexmedetomidine; Fentanyl; Bupivacaine; Infraclavicular Brachial Plexus Block.

1. Introduction:

Regional anesthesia has several reported advantages when compared with general anesthesia for patients undergoing upper limb surgery, including improved perioperative analgesia, improved patient satisfaction and accelerated functional recovery after extremity surgery. (1), reduce analgesic consumption. (2) reduced post-operative nausea and vomiting (PONV) olso shorter post anesthesia care unit stay. (3) and earlier hospital discharge. (4)

Surgeries of the hand and arm are indications for ICB, which is performed at the level of the cords As compared with the supraclavicular approaches, ICB has less impact on pulmonary function but is more likely to spare the radial nerve distribution if a single injection is used. (5)

The infraclavicular approach provides more consistent anesthesia of the axillary and musculocutaneous nerves than the axillary approach, although often at the expense of longer latency. (6)

Infraclavicular brachial plexus block (ICB) is performed between the clavicle and axilla and can be used for surgical procedures performed below midhumerus. Various ultrasound-guided ICB approaches have been reported. (7)

Infraclavicular approach to the brachial plexus block anesthesia is an alternative to general anesthesia for upper extremity surgery. Ultrasound guided infra-clavicular block appears to be associated with high success rate, short onset time and low complication rate. (8)

The use of ultrasound appears to permit accurate deposition of the local anesthetic perineurally, and has the potential to improve the success and decrease the complications of infraclavicular brachial plexus block (9).

Ultrasound imaging during peripheral nerve blockade allows the operator to distribute LA uniformly around the target nerve. This may reduce the amount of LA required to successfully block the nerve so reduce the risk of systemic LA toxicity and other complication. (10).

Dexmedetomidine, is a selective α2-adrenoceptor agonist that is used as an adjuvant mixed with local anesthetics during regional anesthesia Its use in peripheral nerve blocks has recently been described (11).

Opioids are usually used in regional anesthesia, with or without local anesthetics to improve the regional block or postoperative pain control. Opioids have multiple central neuraxial and peripheral mechanisms of analgesic action. Fentanyl are a mu opioid receptor agonist that has been used as adjuvant to local anesthetics to improve efficacy of peripheral nerve block. Since no data are available on fentanyl's effect on the onset time of lidocaine regional anesthesia (12).

2. Patient and methods:

This study was conducted at AL-Azhar University hospitals. Institutional ethical committee approval and informed written consent were obtained from all patients. patients who were ASA physical status I or II, between 18 and 60 years of age, and undergoing an elective below mid humeras surgeries were included. Patients with contraindications to regional anesthesia Patient refusal, Pregnant females, Communication difficulties, which might prevent a reliable postoperative assessment, Diseases affecting sensory or motor function, especially those with diabetic peripheral neuritis or had history of cerebral stroke with lesion affecting side of surgery, patient with upper limb neurological deficit, Allergy to the local anesthetics, Contraindications to infraclavicular nerve block (bleeding disorders (coagulopathy), local or systemic infection), Inability to comprehend the numeric rating scale (NRS) for pain assessment, Body mass index (BMI) > 35. were excluded.

On arrival to the operative room an intravenouscannula (18 or 20 G) will be inserted opposite to the side with will be blocked. Premedication drugs midazolam (0.015 mg/kg) will be given according to preoperative assessment. Reassurance is a good sedation. Oxygen through the nasal catheter will be given through all the procedure. In the operating room non invasive blood pressure (BP), pulse rate, and pulse oximetry (SPO2) were recorded.

Positioning: The patient lied supine with the neck straight and arm adducted with the hand over the abdomen, with the head was turned to the opposite of the blocked side. **Sonoanatomy:** The axillary artery can be identified deep to the pectoralis major and minor muscles. The three cords of the brachial plexus are surrounding the artery: the lateral, posterior, and medial cords.

All patients in the three groups will be assessed and monitored for: I. Sensory Assessment: The sensory block will be tested by cold sensation test **The sensory block was graded as follows:0** = no difference from the unblocked extremity**1**= less cold than the unblocked extremity**2** = no sensation of cold.

II. Motor Assessment: Responses will be elicited from each individual nerve and the motor block was assessed **as follows:0** = no loss of force**1**= reduced force compared with the unblocked extremity**2** = incapacity to overcome gravity.

III. Assessment of Complications: The patients will be assessed for occurrence of any complication that may occur during or after injection: Pneumothorax is rare**,** Infection**,** Nerve injury**,** Hematoma**,** Inadequate pain relief, Nausea and/or vomiting.

IV. Postoperative Pain Score: Using Numerical rating scale (NRS): Its scale for patient self – reporting of pain and it consist of 11 point (0-10), 0 equal (no pain), 10 (most severe pain imaginable). The patients will be asked to select a number ranging from 0 to 10. (13)

The score will be recorded at: In recovery room, Shortly after arrival to Ward (after 30 minutes), After two hours, After 4 hours, After 6 hours, After 12 hours

V. The time of 1st request of analgesia and Total analgesic consumption per twelve hours.

VI. Intraoperative and postoperative sedation scale: By using Ramsey sedation scale

If patient awake

Ramsey 1: Anxious, Agitated and Restless. Ramsey. 2: Cooperative, Oriented and Tranquil. Ramsey

3: Responsive to command only.

Statistical Analysis:

Statistical presentation and analysis of the present study was conducted with SPSS V.20. Data was expressed into two phases:

I – Descriptive:

1- Mean value and Standard Deviation [SD]: for quantitative data- 2- Frequency and percentage for qualitative date.

II -Analytic

F test (0ne way anova): for comparison of more twoindependant quantitative variables normally distributed.

K test (kruskalwallis): for comparison of more two independent quantitative variables not normally distributed.

X2 (Chi 2) test: for comparison between two or more.

Independent qualitative variables normally distributed.

P value > 0.05 was considered statistically non-significant.

P value < 0.05 was considered statistically significant.

P value < 0.001 was considered statistically highly significant.

3. Results:

Demographic data (age, sex, BMI) and operational data (duration of surgery) were statistically comparable among three groups, with mean (age 32.2±9.8, 34.4±10.7, 33.8±11.2 in C, F, D group respectively), (male to female ratio 60%/40%, 51.3%/48.7%, 57.9%/42.1% in C, F, D group respectively), (BMI 24.7±4.5, 25.2±5.2, 24.9±5.2 in C, F, D group respectively). Duration of surgery was (148.6±23.5, 136.5±24.5, 161.7±25.4 in C, F, D group respectively) this can be shown in Table (1).

Table: 1

	C N=18		F N=19		D N=19		F test	P value
Age (years)	32.2±9.8		34.4±10.7		33.8±11.2		0.396	0.674
	N	%	N	%	N	%	0.602*	0.74
Sex Male Female	11 7	60 40	10 9	51.3 48.7	11 8	57.9 42.1		
BMI	24.7±4.5		25.2±5.2		24.9±5.2		0.102	0.903
Duration of surgery in min	148.6±23.5		136.5±24.5		161.7±25.4		0.169	0.845

There were statistically high significant differences (P- value< 0.001) between the three groups regarding the duration of sensory block that can be demonstrated in table (20),. As the statistical analysis by F test showed that, the duration of sensory block was longer in D group (777.6±117.2) when compared with C (235.7±37.9) and F (269.9±39.6) group/.

Table: 2

Sensory block	C	F	D	F test	P value	LSD posthoc
Duration in min	235.7±37.9	269.9±39.6	777.6±117.2	598.1	**<0.001	p^a:0.058 **p^b:<0.001 **p^c:<0.001

p^a: Control &Fent *P-value < 0.05 (statistically significant)

p^b: Control &Dex **P < 0.001 highly statistical significance

p^c: Fent &Dex

The mean duration of motor block in C group was 204±35.6 minutes, in F group 240±40.7 and in D group were 748.7±112.6 minutes. The statistical analysis by F test showed that the difference between duration of motor block in D group was significantly longer when compared to C and F group (P < 0.001) as shown in table (3).

Table: 3

Motor block	C	F	D	F test	P value	LSD posthoc
Duration in min	204±35.6	240±40.7	748.7±112.6	646.3	**<0.001	*p^a:0.04 **p^b:<0.001 **p^c:<0.001

p^a: Control &Fent *P-value < 0.05 (statistically significant)

p^b: Control &Dex **P < 0.001 highly statistical significance

p^c: Fent &Dex

Time to first analgesic request according to VAS > 3 was longer in D 809.2±95.8 minute compared to C 246.3±35.5minute and F 291.2±34.6 groups which was statistically significant (p <0.001) demonstrated in table (4).

Table: 4

Analgesia Duration	C	F	D	F test	P value	LSD posthoc
Duration in min	246.3±35.5	291.2±34.6	809.2±95.8	916.03	**<0.001	*p^a:0.003 **p^b:<0.001 **p^c:<0.001

p^a: Control &Fent *P-value < 0.05 (statistically significant)

p^b: Control &Dex **P < 0.001 highly statistical significance

p^c: Fent &Dex

Table: 5

	C	F	D	K-test	P value	LSD Posthoc
Total Analgesic Consumption (Ketorolac in mg)	50±26	47±26	18±18	8.9	**<0.001	*p^a:0.019 **p^b:<0.001 p^c:0.07

p^a: Control &Fent
p^b: Control &Dex
p^c: Fent &Dex

*P-value < 0.05 (statistically significant)
**P < 0.001 highly statistical significance

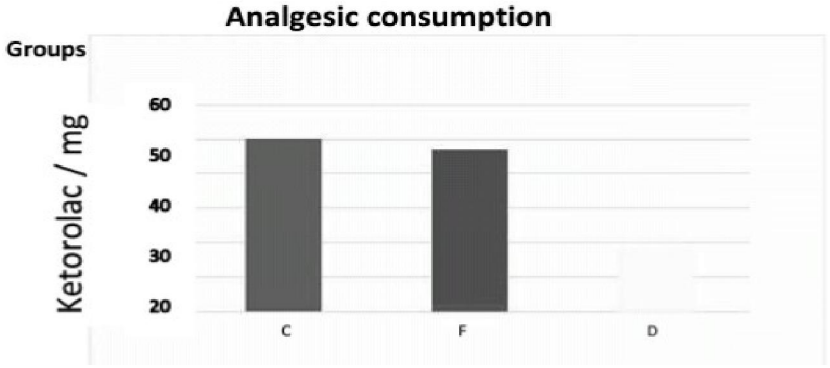
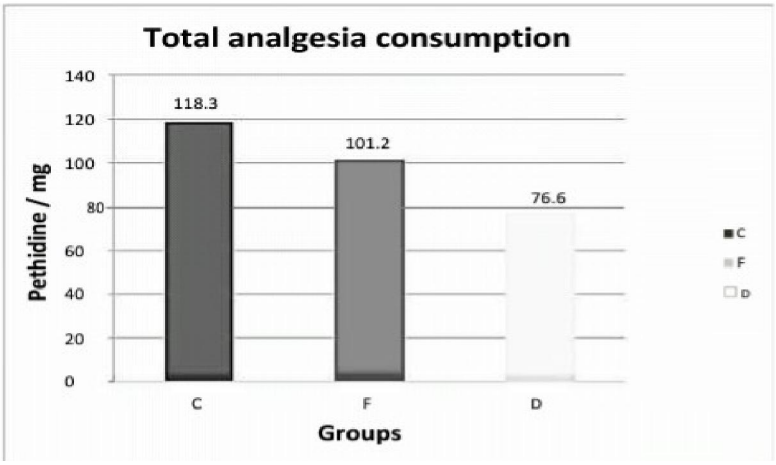


Table: 6

	C	F	D	K-test	P value	LSD posthoc
Total analgesic consumption Pethidine/mg	118.3±35.1	101.2±23.6	76.6±29	7.8	**<0.001	*p^a:0.011 **p^b:<0.001 p^c:0.06

p^a: Control &Fent
p^b: Control &Dex
p^c: Fent &Dex

*P-value < 0.05 (statistically significant)
**P < 0.001 highly statistical significance



By comparing intraoperative heart rate among the groups there were no statistically significant differences in this parameter at 15, 30, 60 minutes. But at 90 minutes there was statically significant difference between groups as HR was lower in D group but the difference was not clinically significant. This can be shown in Table (7).

Table: 7

HR	C	F	D	F test	P value
Baseline	82.4±7.3	82.3±7.3	82.5±7.3	0.01	0.99
15 min	79.4±5.9	79.2±4.9	79.3±5.2	0.023	0.977
30 min	77.8±4.1	78.7±4.5	77.5±4.4	0.768	0.467
60 min	77.5±4	77.9±3.9	77.1±4.1	0.385	0.681
90 min	78±3.4	78.6±4	76.4±4.1	3.1	0.049

*P-value < 0.05 (statistically significant) **P < 0.001 highly statistical significance

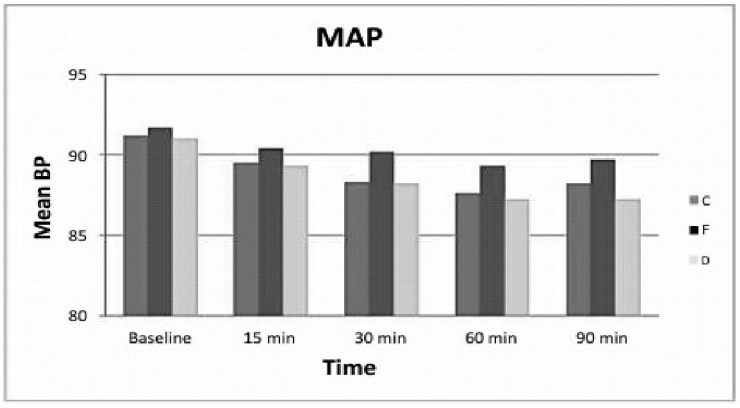
In group D, the mean arterial blood pressure ranged from 91±5.9 to 87.2±4.3 mmHg, group F from 91.7±5.3 to 89.7±4 and group C, the mean arterial blood pressure ranged from 91.2±5.5 to 88.2±4.2 mmHg. Statistical analysis by F test showed that there was no significant difference in systolic blood pressure between the two groups (P > 0.05) shown in table (8).

Table: 8

MAP	C	F	D	F test	P value
Baseline	91.2±5.5	91.7±5.3	91±5.9	0.173	0.841
15 min	89.5±5.5	90.4±4.9	89.3±5	0.508	0.603
30 min	88.3±4.7	90.2±4.8	88.2±4.1	2.2	0.112
60 min	87.6±5.1	89.3±4.6	87.2±4.3	2.1	0.127
90 min	88.2±4.2	89.7±4	87.2±4.3	3.3	0.04

*P-value < 0.05 (statistically significant)

**P < 0.001 highly statistical significance



By comparing intraoperative oxygen saturation among the groups there were no statistically significant differences in this parameter this can be demonstrated in Table (9).

Table: 9

O2 Saturation	C	F	D	F test	P value
Baseline	98.4±0.9	98.4±0.9	98.4±0.9	0.001	0.999
15 min	98.4±0.9	98.4±0.9	98.4±0.9	0.001	0.999
30 min	98.4±0.9	98.4±0.9	98.4±0.9	0.001	0.999
60 min	98.4±0.9	98.4±0.9	98.4±0.9	0.001	0.999
90 min	98.4±0.9	98.4±0.9	98.4±0.9	0.001	0.999

*P-value < 0.05 (statistically significant)

**P < 0.001 highly statistical significance

As the dexmedetomidine has sedative effect, the total sedative consumption (propofol / mg) was significantly lower in D group than other two groups as described in table (10).

Table: 10

	C	F	D	K-test	P value	LSD posthoc
sedative consumption (propofol in mg)	409±132	398±131	379±136	318.9	**<0.001	*p^a:0.014 **p^b:<0.001 p^c:0.09

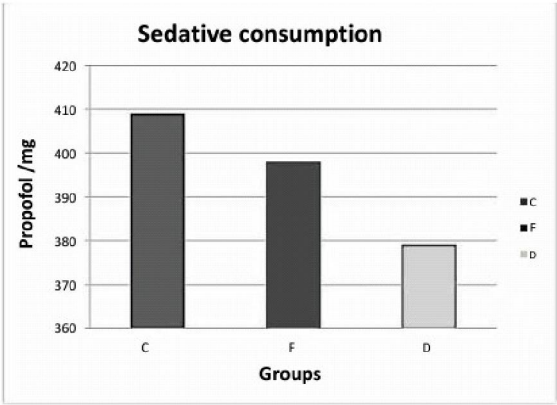
p^a: Control &Fent

p^b: Control &Dex

p^c: Fent &Dex

*P-value < 0.05 (statistically significant)

**P < 0.001 highly statistical significance



The mean RSS in group D was (2.5±0.5 and 2.1±0.5) at 15, 30 min which was significantly higher than group C (1.9±0.3 and 1.9±0.5) and group F (2±0.4 and 1.8±0.3) respectively, illustrated in table (11).

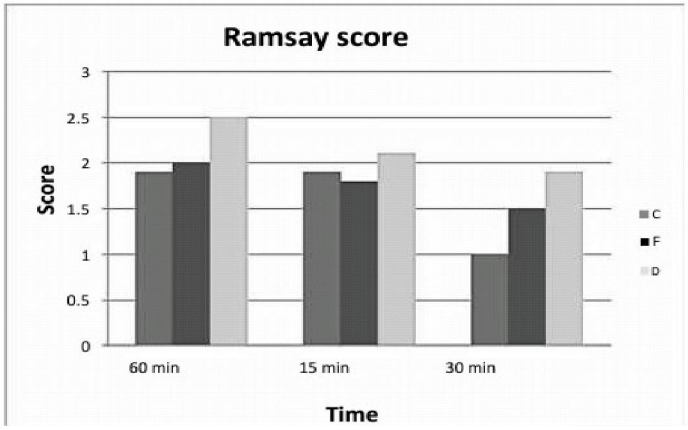
Table: 11

RAMSY	C	F	D	F test	P value	LSD posthoc
15 min	1.9±0.3	2±0.4	2.5±0.5	18.4	**<0.001	*p^a:0.03 **p^b:<0.001 **p^c:<0.001
30 min	1.9±0.5	1.8±0.3	2.1±0.5	12.9	**<0.001	p^a:0.185 **p^b:<0.001 **p^c:<0.001
60 min	1.8±0.4	1.5±0.4	1.9±0.3	---	---	

p^a: Control &Fent *P-value < 0.05 (statistically significant)

p^b: Control &Dex **P < 0.001 highly statistical significance

p^c: Fent &Dex



Lower VAS pain scores was recorded in D group and were statistically significant at 2nd, 3rd, 4th and 5th reading, shown in table (12).

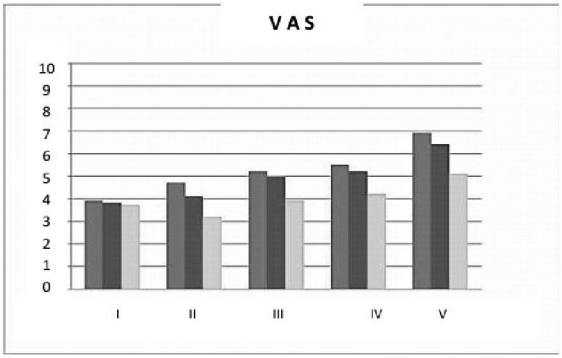
Table: 12

VAS	C	F	D	F test	P value	LSD Posthoc
I	3.9±0.8	3.8±0.8	3.7±0.7	0.657	0.521	p^a:0.798 p^b: 0.279 p^c: 0.402
II	4.7±1.6	4.1±1.5	3.2±1.3	9.8	**<0.001	p^a:0.07 **p^b:<0.001 *p^c: 0.01
III	5.2±1.8	4.97±1.7	3.9±1.2	7.03	**<0.001	p^a:0.549 *p^b:0.001 *p^c: 0.004
IV	5.5±1.7	5.2±1.5	4.2±1.9	5.7	*0.004	p^a:0.384 *p^b:0.002 *p^c: 0.018
V	6.9±1.8	6.4±1.8	5.1±1.9	9.1	**<0.001	p^a:0.336 **p^b:<0.001 *p^c: 0.002

p_a: Control &Fent *P-value < 0.05 (statistically significant)

p_b: Control &Dex **P < 0.001 highly statistical significance

p_c: Fent &Dex



Two patients developed hypotension (mean arterial blood pressure decrease by 20% or more from the baseline) in D group with no patients in other groups with any significant difference. Three patients in D group developed bradycardia (heart rate decrease by 20% or more from the baseline) with high significant difference decrease than other groups shown in table (13).

Table: 13

	C		F		D			
Complications	N(18)	%	N(19)	%	N(19)	%	X2	P value
Hypotension	0	0	0	0	1	0.5	4.07	0.131
Bradycardia	0	0	0	0	3	17.5	**14.9**	***<0.001**
Dysnea	0	0	0	0	0	0	---	--
Drug Overdose	0	0	0	0	0	0	---	--
Intravascular Injection	0	0	0	0	0	0	--	--

*P-value < 0.05 (statistically significant)

**P < 0.001 highly statistical significance

4. Discussion:

Ultrasound technology can offer accurate localization of the nerve and the distribution of local anesthetic. (14)

Different additives have been used to prolong duration of blockade and so improve the quality of anesthesia and postoperative analgesia. (15)

Many studies were done for the safest and effective dose of dexmedetomidine as adjuvant to local anesthetic in brachial plexus block as Mirkheshti and his colleagues. in their study used 100ug dexmedetomidine as additive in Infraclavicular block. (16)

Other additives were used in brachial plexus block. Opioids are considered as cornerstone for treatment of pain following surgery. Furthermore, it is reported that opioid antinociception can be initiated by activation of peripheral opioid receptors. It is reported that fentanyl has a local anesthetic action. (17)

The addition of opioids to local anesthetics injected into brachial plexus network was shown to increase the success rate and postoperation analgesia by some authors, whereas others have found no effect. (18)

One of the most popular opioid used as additive in regional El-Radaideh and his colleagues used fentanyl 1µg kg added to mixture of lidocaine and bupivacaine in Infraclavicular block. (19) Sarkar and his colleagues added 50ug fentanyl to mixture of local anesthetics (lidocaine and bupivacaine). (20)

In the present study 18 ml 0.5% bupivacaine was used plus 2 ml either (2ml saline or 100ug fentanyl or 100ug dexmedetomidine) with total volume 20 ml, this was near to volume used by most of studies of Infraclavicular block as (Lomate and his collogues. used 30 ml of 0.5% bupivacaine and xylocaine. (21), Ammar and his colleagues used 30 ml 0.33% bupivacaine also. (22) and Mirkheshti and his colleagues used 25ml lidocaine 1.5% plus 5 ml of additive in total volume 30 ml). (23)

In our study we used double injection technique, 12 ml at posterior cord and 8 ml at lateral cord and studied their effect on onset and duration of sensory and motor block, duration of analgesia, total analgesic consumption, VAS score and complications.

The present research revealed that onset of block was enhanced in D group than C and F groups.

The current study showed that dexmedetomidine causes significant increase in the duration of sensory block, motor block and analgesia when added to bupivacaine, the mean duration of sensory block, motor block and analgesia was (777.6±117.2, 748.7±112.6, and 809.2±95.8 min). The durations in C group were (235.7±37.9, 204±35.6 and 246.3±35.5) respectively and F group (269.9±39.6, 240±40.7 and 291.2±34.6mins). The durations in F group were significantly longer than C group but significantly lower than the prolongation in D group.

The current study is consistent with the results of Gandhi and his colleague who used dexmedetomidine along with bupivacaine for brachial plexus block. The study included two groups Control group-C received injection of bupivacaine (0.25%) 38 milliliter plus 2 milliliter normal saline, dexmedetomidine group-D received injection bupivacaine (0.25%) 38 milliliter plus dexmedetomidine 30 microgram (2 milliliter). The study showed that the duration of sensory block in Dex (732.4 ± 48.9) was statistically longer than cont (146.5 ± 36.4) (< 0.0001), also duration of motor block Dex (660.2 ± 60.4) and Cont (100.7 ± 48.3) (< 0.001). The duration of analgesia in dexmedetomidine group-D is (732.4 ± 95.1) minute, which is statistically

significant (p <0.000) longer than control group (194.8 ± 60.4) minute. (24)

In consistence to current study Yaghoobi in their study found that duration of sensory block in LF (139 ±22.89 min) was significantly longer than group L (106± 18.03min) and duration of motor block in LF (147± 24. 62min) longer than L group (119 ± 20.84min). (25)

In contrast to the current study Sarkar and his colleagues showed no significant difference in sensory block duration between cont and Fent groups (217± 48.56 and 225.12±34.0) respectively, also no significant difference in motor block duration between Cont and Fent groups (287.76± 44.62 and 294.16 ± 55.69) respectively. Analgesia duration was significantly longer in Fent than Cont group (493.28 ± 152.45 and 448.32± 147.69) respectively. (26)

Current study showed lower rescue pethidine requirements 24 h after surgery in Dex group (95.7±34) than Cont and Fent groups (129.3±38.1 and 110.1±29.7mg) respectively.

Consistent with current study, Lomate showed that postoperative distribution of patients according to VAS ≥ 4 (fig.1) shows that all patients in group C required rescue analgesia by 14 hours; whereas in group D the same was true only after 34 hours. (27)

The current study showed that the three groups were comparable in vital parameters (mean blood pressure, heart rate, and oxygen saturation) with two cases developed hypotension in Dex group and none of patients developed hypotension in other groups and 7 patients developed bradycardia which was treated with atropine in Dex groups with no cases in other groups.

Recommendations:

We recommend usage of ulratrasound in performing brachial plexus block as a routine because of accurate deposition of the local anesthetic perineurally, a high success rate and low complication rate.

Addition of dexmedetomidine to regional anesthesia when prolongation of anesthesia and postoperative analgesia is desired as it enhances the onset and prolongs the sensory and motor block significantly

In elderly patients and patients with cardiovascular comorbidities when low dose local anesthetic is recommended, Dexmedetomidine can be a good additive to local anesthetic, however, further studies may also be warranted.

Lower doses and volume of local anesthetic with double injection Infraclavicular block versus higher volume with single injection under guide of ultrasound.

Although no major neurological complications have been reported so far, further studies are required to rule out any short term or long term adverse effects.

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10/27/2017