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RESEARCH ARTICLE

"Evaluation of efficacy of Tramadol as an adjuvant to Lignocaine in Intravenous Regional Anaesthesia for upper limb surgeries"

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Abstract

Introduction- Intravenous Regional Anaesthesia (IVRA) is a type of regional anaethesia in which the limb is isolated from the systemic circulation by means of tourniquet. IVRA is particularly advantageous to use in critically ill patients having undercurrent systemic disease, associated head and neck injury, patient that are not fit for general anaesthesia and also in patients with full stomach requiring emergency surgery. It provides adequate intraoprerative analgesia and muscle relaxation. Recently various adjuvants have been used along with local anaesthetics to improve postoperative analgesia like pentazocine, ketorolac, morphine, meperidine, fentanyl, tramadol, dexmetedomidne, clonidine, and buprenorphine. With this back ground, the present study was conducted to assess the efficacy of Tramadol as an adjuvant to Lignocaine in Intravenous Regional Anaesthesia for upper limb surgeries.

Material and Method- 60 Patient of either sex, between age group of 16 to 60 years and ASA I and II were included in the study. The patients were allocated into two groups (group A and B) depending upon the drug injected intravenously for IVRA. Group A consisted of 30 patients who received 0.5%, 40 ml Lignocaine plus 1 ml NS, Group B consisted of 30 patients who received 0.5%, 40 ml Lignocaine with Tramadol 50 mg in IVRA.

Onset of sensory & motor blockade after injection of drug following tourniquet inflation, quality of block, recovery of sensory and motor blockade, duration of postoperative pain after tourniquet deflation was also assessed. The result of this study was subjected to statistical analysis for significance. The statistical methods employed were unpaired-t test and 'p' value.

Results- Majority of the patients in group A & B were in the age group of 16-35 year. The majority of the patients were male in both the groups. The mean onset of sensory blockade was 4.48 ± 0.99, 2.36 ± 0.507 minutes in group A & B respectively. The mean onset of motor blockade was 11.56 ± 1.35, 11.5±1.07 minutes in group A & B respectively. Block was excellent in 23 cases (76.66%) in group B, as compared to 11 cases (36.66) in group A.

Conclusion- On the basis of results obtained in the present study, it can be concluded that addition of tramadol to lignocaine in IVRA shortens the onset & prolongs the recovery of sensory blockade. This combination has definitive advantage in prolonging to postoperative analgesia up to 3 hrs.

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INTRODUCTION

Intravenous Regional Anaesthesia is a type of regional anaethesia in which the limb is isolated from the systemic circulation by means of tourniquet. Then local anaesthetics are injected intravenously which diffuses retogradely from the veins to nerve endings. It is simple to administer, reliable with almost 95-100% success rate, cost effective and provides profound intraoperative analgesia.

IVRA is particularly advantageous to use in critically ill patients having undercurrent systemic disease, associated head and neck injury, patient that are not fit for general anaesthesia **(Holmes, 1963)** and also in patients with full stomach requiring emergency surgery **(Fleming SA, 1969)**. **[1, 2]** It provides adequate intraoprerative analgesia and muscle relation. IVRA has some added advantages over nerve block, i.e. easy to perform and even an anesthesiologist with little experience can perform it, rapid onset along with almost nil failure rates, cost effectiveness and useful for outpatients, as patients can be allowed to go home after surgery. It provides bloodless field for surgery and also avoid the risk of pneumothorax, a complication that can occur with brachial plexus blocks. Recently various adjuvants have been used along with local anaesthetics to improve postoperative analgesia like pentazocine, ketorolac, morphine, meperidine, fentanyl, tramadol, dexmetedomidne, clonidine, and buprenorphine.

The results of various studies were not uniform & in fact conflicting therefore it was thought worth-while conducting a study using Tramadol Hydrochloride, a synthetic opiod and commonly used analgesic, with Lignocaine for IVRA to observe its usefulness in respect of onset and quality of sensory and motor blockade and prolongation of postoperative analgesia.

MATERIALS AND METHODS:-

The present prospective study was carried out in 60 patients in Pt. J. N. M. Medical College and Dr. B.R.A.M. Hospital Raipur (C.G.) for surgery of forearm and hand, with approval from institutional ethical committee. Duration of study was 1 years from Nov 2007 to Oct 2008.

Patient of either sex, between age group of 16 to 60 years and ASA I and II were included in the study.

Patients with known hypersensitivity to local anaesthetics; serve peripheral vascular disease and neurological disease; where use of tourniquet was either not possible or contraindicated; haemolytic diathesis specially sickle cell anemia; epilepsy; hypertension; cardiovascular disease; altered mentation were not included in the study. Preanaesthetic checkup done. Anaesthesia equipments with all drugs were kept ready to deal with any emergency situation.

Patients were randomly allocated in to two groups A & B (n=30 in each group) as follows:

Group A	Lignocaine 0.5% 40 ml (preservative free)+ NS 1ml
Group B	Lignocaine 0.5% 40 ml + Tramadol 1ml (50mg)

A padded double cuff tourniquet was positioned around the arm on the side to be operated and tested. A 22 G IV canula was placed for drug injection in peripheral vein preferably over the dorsum of the hand and secured in position. Now the limb was exsanguinated by elevating it to 90 degrees for 3 minutes and brachial artery compression technique. Then proximal tourniquet cuff inflated to a pressure of 50-75 mm Hg above the patient's systolic blood pressure and time was recorded. Circulatory isolation of the fore-arm was verified by inspection. Absence of redial pulse and loss of pulse oximetry tracing of the ipsilateral index finger. This criteria was fixed for all the cases of the study. Then a total dose of 40 ml 0.5% lignocaine was injected slowly either with NS 1ml (group A) or with tramadol 50 mg 1ml (Group B) depending upon the group as mentioned earlier. During the period of injection patients were frequently asked for any unwanted feeling of sensations.

NIBP, Pulse Rate and Respiratory Rate, SpO2 were recorded immediately after the drug injection and then every 5 minutes. After establishment of complete analgesia distal cuff was inflated to a pressure of 50-75 mm Hg

above the patients systolic blood pressure followed by deflation of proximal cuff to avoid any tourniquet discomfort, and surgeon allowed to start surgery. Throughout the procedures tourniquet pressure was monitored and maintained.

Following completion of Surgery tourniquet cuff was deflated with repeated deflation-reinflation technique, for this cuff was deflated for 10 sec and then reinflated again for 1 min. This sequence was repeated three times. Caution was taken not to deflate the cuff within 30min of local anesthetic injection in any case, to avoid local anesthetic toxicity & not to keep the cuff inflated for more than 90 min. Even if the the surgical procedure was over within 30 min the tourniquet was not deflated before 30 min. This was strictly observed throughout the study. After deflation of tourniquet cuff haemodynamic changes & any complication or side effect were observed every 5 min for at least 30 min in recovery ward. Patients were also assessed for recovery of sensory & motor blockade. Thereafter patients were followed up to 48 hours for delayed neurological squeal.

Onset of sensory & motor blockade after injection of drug following tourniquet inflation, quality of block, recovery of sensory and motor blockade, duration of postoperative pain after tourniquet deflation was also assessed.

As described by urban B.J. and Mckain C.W, Assessment of sensory blockage was mapped out in every case. **[3]**

The time taken from injection of drug to loss of pinprick sensation was taken as onset of sensory blockade. If there was loss of pinprick sensation in all six skin areas tested, it was considered as complete sensory blockade.

Patients were asked to make finger movements and dorsiflexion at wrist joint. Inability to do was taken as motor blockade. The time taken from completion of injection of drug to inability to make finger and wrist movement, was recorded as complete motor blockade.

Time from the inflation of proximal cuff to deflation of distal cuff was designated as total tourniquet time and it was recorded in every case.

The quality of overall block was assessed according to the grading (Excellent, Good, Fair and poor) as per standard protocol.

Assessment of Intra-operative & Post-operative pain –was rated on a Visual analog Scale (VAS) graded from 0 cm (no pain) to 10 cm (unbearable pain).

All the data pertaining to the study observed were recorded in the specially prepared proforma for the study. The relevant literature was reviewed and the observation of the study were compared and contrasted with those of other workers and discussed.

The result of this study was subjected to statistical analysis for significance. The statistical methods employed were unpaired-t test and 'p' value.

If 'p' value is <0.05 then difference between the two sets of observation will be considered significant.

OBSERVATION

The patients were allocated into two groups (group A and B) depending upon the drug injected intravenously for IVRA. Group A consisted of 30 patients who received 0.5%, 40 ml Lignocaine plus 1 ml NS, Group B consisted of 30 patients who received 0.5%, 40 ml Lignocaine with Tramadol 50 mg in IVRA.

Table-1. Back ground characteristics of study subjects

Background variables	**No. of Cases**			
	Group A		**Group B**	
	N=30	**%**	**N=30**	**%**
Age (in years)				
16-25	15	50	14	46.67
26-35	10	33.34	08	20.67
36-45	01	3.34	06	20
46-55	04	13.36	02	6.69
Mean ±SD	28.86 1±0.97		28.96 ±11.33	
Sex				
Male	24	80	22	73.33
Female	6	20	8	26.67
Weight (in Kg.)				
46-50	02	6.66	04	13.33
51-55	12	40	07	23.33

56-60	16	53.33	16	53.33
61-65	00		03	10
Mean ±SD	55.7 ±2.25		56.73 ±4.33	
Nature of Surgery				
Routine	23	76.67	16	53.33
Emergency	07	23.33	14	46-61

Majority of the patients in group A & B were in the age group of 16-35 year. The majority of the patients were male in both the groups. Means weight of patients in group A & B was 55.7 + 2.25 & 56.73 + 4.33 Kgs respectively. Majority of cases were operated as routine procedures i.e. 39 (65%) cases as compared to 21 (35%) cases operated as emergency procedures. **[Table-1]**

Table-2. Comparison of both groups on basis of different parameters

Variables	**Total No. of Cases**			
	Group A		**Group B**	
	N=30	**%**	**N=30**	**%**
Onset time (Minutes) of Sensory Blockade				
1.1-1.5	0	0	01	3.33
1.6-2.8	0	0	14	47.33
2.1-2.5	0	0	05	16.67
2.6-3.0	0	0	10	33.33
3.1-3.5	0	0	0	0
3.6-4.0	13	43.33	0	0
4.1-4.5	06	20	0	0
4.6-5.0	11	36.66	0	0
Total	30	100	30	100
Mean ±SD	4.48 ±0.99		2.36±0.507	
t-Value	3.13			
P Value	<0.001			
Onset time (Minutes) of motor Blockade				
9.1-11	13	43.33	14	46.66
11.1-13	15	50	16	53.33
13.1-15	01	3.33	00	00
15.1-17	01	3.330	00	00
Mean ±SD	11.56 ±1.35		11.5 ±1.07	
t-Value	0.8336			
P Value	P>0.05			
Grading of Quality of Blockade				
Excellent	11	36.66	23	76.56
Good	10	33.33	07	23.33
Fair	09	30	00	00
Poor	00	00	00	00
Tourniquet time (Minutes)				
30-45	11	36.66	23	76.56
46-60	10	33.33	07	23.33
61-75	09	30	00	00
Mean ±SD	51.83 ±6.88		53.8 ±4.61	
t-Value	0.191			
P Value	>0.05			
Recovery time (min.) of sensory blockade				

3-4	12	40	0	
5-6	18	60	13	43.33
7-8	00	00	17	56.66
Mean ±SD	4.73 ±0.99		6.53 ±0.75	
t-Value	4.76			
P Value	>0.001			
Recovery time (Min) motor blockade				
1-2	04	13.33	12	40
3-4	21	70.00	07	23.33
5-6	05	16.66	11	36.66
7-8	00	00	00	00
Mean ±SD	3.56 ±0.935		3.46 ± 1.40	
t-Value	0.74			
P Value	>0.05			
Duration (in hour) of postoperative analgesia				
0-1	30	96.66	00	0
1.1-2	1	3.33	11	36.66
2.1-3	00	00	19	63.33
Mean ± SD	0.658 ± 0.24		2.51 ± 0.0.444	
t-Value	0.880			
P Value	<0.0001			

The mean onset of sensory blockade was 4.48 ± 0.99, 2.36 ±0.507 minutes in group A & B respectively. Shortest time of onset was 1.5 minutes & longest was 5 minutes. (p<0.001) The majority of patients in group A (28 cases, 93.33%), in group B (30 cases, 100%) developed motor blockade in 9-13 minutes. The mean onset of motor blockade was 11.56 ± 1.35, 11.5±1.07 minutes in group A & B respectively. Block was excellent in 23 cases (76.66%) in group B, as compaired to 11 cases (36.66) in group A. It was good in 7 cases (23.33) in group B & 10 cases (33.33) in group A. It was fair in 09 cases in group A. The quality of sensory blocked was not found to be poor in any case in both the group. The minimum duration for which the tourniquet was kept inflated was 30 minutes & maximum time was 65 minutes in all 60 cases in this study. Mean tourniquet time in group A & B was 51.83 ± 8.2 & 53± 4.61 minutes respectively.

The majority of patients 18 (60%) had recovery of sensory blockade within 5-6 minutes in group A & 7-8 minutes in group B (17 patients, 56.66%). The mean recovery of sensory blockade was 4.73 ± 0.99 minutes & 6.53± 0.75 minutes in group A & B respectively. The shortest time of recovery was 3 min & longest was 8 min. (p <0.001) The mean time for motor blockade recovery following release of tourniquet was 3.56 ± 0.935 min & 3.46 ± 1.4 min in group A & B respectively. In all the patients in group A analgesic duration did not last for more than one hour i.e. mean duration was 0.658 ± 0.24 hours. In group B mean postoperative analgesia was 2.51 ± 0.444 hours. (p<0.0001) **[Table-2]**

Table-3. Comparison of both group on the basis of Pulse rate, Blood pressure, Respiratory rate and Spo2

Parameters	**Group A**				**Group B**				**t Value A<->B**	**p Value**
	Mean	**SD**	**T value**	**P Value**	**Mean**	**SD**	**t value**	**P Value**		
Pulse rate (per min.)										
Pre operative	88.66	6.51	-	-	83.27	5.03	-	-	0.017	>0.05
After inflation of tour & Inj of drug	8.66	6.51	0.325	>0.05	81.48	5.00	1.56	>0.05	0.001	>0.05
After deflation of tour	86.6	6.51	0.325	>0.05	82.30	4.87	0.27	>0.05	0.006	>0.05
Systolic BP(in mmHg)										
Pre operative	111.4	9.72	-	-	112.6	4.78	-	>0.05	0.33	>0.05
After inflation of tour & Inj of drug	111.4	9.72	0.325	>0.05	112.4	8.95	0.94	>0.05	0.66	>0.05

After deflation of tour	111.4	9.72	0.325	>0.05	111.1	9.59	0.47	>0.05	0.89	>0.05
Diastolic BP(in mmHg)										
Pre operative	74.2	9.9	-	-	72.6	7.65	-	-	0.79	>0.05
After inflation of tour & Inj of drug	74.2	9.3	0.32	>0.05	74.0	9.11	0.57	>0.05	0.93	>0.05
After deflation of tour	74.2	9.31	0.32	>0.05	72.2	8.31	0.83	>0.05	0.41	>0.05
Respiratory rate										
Pre operative	15.9	1.5	-	-	17.0	1.2	-	-	0.547	>0.05
After inflation of tour & Inj of drug	15.9	1.5	0.325	>0.05	15.9	1.5	0.001	>0.05	1.00	>0.05
After deflation of tour	15.9	1.5	0.325	>0.05	15.6	1.2	0.001	>0.05	0.29	>0.05
Spo2										
Pre operative	98.8	1.06	-	-	98.8	1.06	-	-	0.46	>0.05
After inflation of tour & Inj of drug	98.8	1.06	0.32	>0.05	98.8	1.06	0.16	>0.05	1.00	>0.05
After deflation of tour	98.8	1.06	0.32	>0.05	98.9	1.03	0.16	>0.05	0.54	>0.05

The mean pulse rare preoperative was 88.66 ± 6.51 per minute in group A & 83.27 ± 5.03 per min. in group B patients. The mean pulse rate intraoperatively after inflation of tourniquet & the release of tourniquet was close to the base line i.e. preoperative value. The mean systolic blood pressure preoperative was 111.4 ± 9.72 mmHg & 112.6 ± 4.78 mmHg in group A & B respectively. The mean DBP preoperative was 74.2 ± 7.65 in group B patients. The mean respiratory rate preoperative was 15.9 ± 1.5 & 17 ± 1.2 per minutes in group A & B patients respectively. The mean SpO2 preoperative was 98.6 ± 1.06 in group A & B patients. **[Table-3]**

Table-4. Side effects in both group observed during the procedure

Side Effect	Group A		Group B	
	N=30	%	N=30	%
Nausea/ vomiting	0	0	1	3.33
Pruritus	0	0	0	0
Res. Depression	0	0	0	0
Tinnitus	0	0	0	0
Numbness	0	0	0	0
Skin rash	0	0	1	3.33
Convulsion	0	0	0	0

Only one pts in group B showed symptom of nausea & vomiting & in another one pts skin rash was observed after deflation of tourniquet. None of the pts in group A showed any of the above mentioned complication or side effect. **[Table-4]**

Discussion

Intravenous Regional Anaesthesia (IVRA) is now an established technique of anaesthesia. The long experiences, in the last 4 decades has established its utility in poor risk, ill prepared and full stomach patients. This technique provides effective analgesia for surgery in extremities with very high rate of success. IVRA technique was basically described with local anaesthesic agent, but later impressed with its efficacy, other adjuvant such as opioids and muscle relaxants have been tried to improve the quality of analgesia and extend the analgesia to the post operative period.

Mean weight of patients in group A and B was 55.7 ± 2.27 and 56.73 ± 4.43 kgs, respectively in the present study. Goel s N et al 2001 patients' average weight in their study was 57-58kgs. **[4]** Raafat M et al 2005 patients' average weight in their study was 69-74Kgs. **[5]**

Ware R J 1979, Sukhani et al 1989, Goel S N et al 2002, and Rodola F et al 2003 used double cuff tourniquet and found it to be extremely effective. **[4, 6, 7, 8]** In our study, a double cuff pneumatic tourniquet was found to be quite effective in abolishing tourniquet discomfort. Enright A.C. et al 1980 used tourniquet pressure up to 300mm Hg. **[9]** Ware RJ 1979 used still lower pressure i.e. 50 mmHg above the patient's systolic blood pressure. **[6]** In our study, the pneuniquet pressure 50-75 mmHg above the patient's systolic blood pressure was found to be effective & satisfactory, as observed by Ware R J 1979 & Achalovschi et al 2001 in their study. **[6, 10]** In this study the mean onset time in group A & B was 4.48 ± 0.99 min & 2.36 ± 0.507 min, respectively. The difference in mean onset time between group A & B was statistically significant ($p<0.001$).

Siddiqui A K et al 2008 showed that lignocaine with tramadol had earlier onset of sensory block (5.2 ± 1.2 min & 4.9 ± 1.2 min in the T50 & T100 groups, respectively) compared with lignocaine alone (7.6 ± 1.4min).**[11]** Our findings were very well correlated with their findings. This might be because of modification of the action of local aneasthetic and additive local anaethetic property of tramadol. Acalovschi et al 2001 had reported complete motor blockade in 14.5 min in lignocaine group & 11.8 min in lignocaine with tramadol group. Tan S M et al 2001 reported faster onset of sensory & motor blockade in lignocaine with tramadol group, though it was not significantly different from lignocaine group. Raafat M et al 2005 had reported complete motor blockade in 15 (3) min & 10 (3) min in lignocaine and lignocaine with tramadol (100mg) group, respectively. **[10, 12]** In our study, the onset of motor blockade was not affected by addition of tramadol in IVRA. Tan S M et al 2001 showed that tramadol might improve the quality of IVRA. Aclovaschi I et al (2001) demonstrated that tramadol improve the onset & degree of block when used as an adjuvant to lignocaine in IVRA. In our study quality of blockade were also excellent in most of patients in lignocaine with tramadol group (23, 76%) than linocaine alone (11, 36.66%) might be because of additive effect with lignocaine. The difference in the mean sensory recovery time in between group A & B was statistically significant ($p<0.001$). Acalovaschi 1 et al 2001 showed that recovery for touch sensation was prolonged in lignocaine with tramadol group than lignocaine alone. Mean (SD) AUC for touch sensation was 19.5 (6.5) & 11.6 (5.5) respectively, it was statistically significant ($p<0.05$). Raafat M et al 2005 showed that recovery time of sensory blockade in lignocaine with tramadol was 4 (1) min & in lignocaine alone 4 (2) min. Thus recovery of sensory blockade prolonged in our study corresponds to the findings of above workers. Raafat M et al 2005 had reported complete motor block recovery time in lignocaine with tramadol group was 5 (1) min in both. In our study also tramadol had not affected the recovery of motor blockade. **[5, 10, 12]**

Sukhani et al 1989 mentioned deflation-reinflation technique as an effective method of tourniquet deflation to prevent high peak concentration of local anaesthetic in circulation & thus toxicity. **[7]** In our study also observed the same with deflation reinflation technique.

So K Y et al 2002 showed that addition of tramadol to lignocaine in IVRA improve postoperative analgesia. Goel S N et al 2002 demonstrated that the mean onset time to first to first analegesic requirement was 12.7 ± 8.62 & 16.8 ± 9.07 hrs in lignocaine alone (Group A) & lignocaine with tramadol 50 mg (Group B) , respectively . The difference in mean postoperative analegesia between group A & B was statistically significant ($p<0.05$). Raafat M et al 2005 observed the duration of postoperative analgesia in their study was 210 (47) min., 289 (91) min, 215 (82) min and 217 (81) min in lignocaine alone & with addition of dexmedetomidine, sufentanyl and tramadol, respectively. **[4, 5, 13]** In our study, postoperative analgesia was also prolonged significantly in group B than Group A and correlated with findings of the other studies. The increase in duration of postoperative analgesia might be due to persistent activation of peripheral opioid receptors.

The minimum duration for which the tourniquet was kept inflated in this study was 30 minutes & maximum time was 65 minutes. Mean tourniquet time was 51.83 ± 6.88 & 53.8 ± 4.61 minutes in group A & B, respectively. Many workers (Raafat M et al 2005, John M 2008) strongly advocated that the release of tourniquet should never be done earlier that 20-30 min. following injection of local anesthetic agent to avoid local anaesthetic toxicity and not to keep the cuff inflated for more than 90min to avoid tourniquet related complications. **[5, 14]**

In this study pulse rate, Blood Pressure, Respiratory Rate & SpO2 of all the patients in two groups were monitored intraoperatively and there were no significant changes in these parameters either in intraoperative or immediate postoperative period, when compared to preoperative values.

Many studies like Goel S N et al 2002, Raafat M et al 2005 & John M et al 2008 demonstrated that there were no significant changes in these parameter from base-line value. **[4, 5, 14]**

CONCLUSION

On the basis of results obtained in the present study, it can be concluded that addition of tramadol to lignocaine in IVRA shortens the onset & prolongs the recovery of sensory blockade. This combination has definitive advantage in prolonging to postoperative analgesia up to 3 hrs. (Quality of analgesia). The findings of the present study will be useful for anaesthetists to choose appropriate combination of drugs during the procedure for effective outcome. The findings will be also useful for researchers in similar kind of study.

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