Pain Relief and Post-Operative Outcome in Patients Receiving Tramadol via Thoracic Epidural versus Intravenous Method in Coronary Artery Bypass Graft Surgery

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Abstract

Background & Objectives: Acute pain is common after cardiac surgery and can keep patients from participating in activities that prevent postoperative complications especially respiratory complications. Accurate assessment and understanding of pain are vital for providing satisfactory pain control and optimizing recovery.

Our aim of the study was to compare pain relief and post-operative outcome in patients receiving Tramadol via Thoracic epidural versus intravenous method in coronary artery bypass graft surgery.

Methodology: Sixty patients aging 40-65 years posted for off pump coronary artery bypass graft surgery were selected. They were randomly assigned into two groups. Group IVA (n = 30) received Inj. Tramadol (1 mg/kgiv)and Group TEA (n = 30) received Tramadol 0.5 mg/kgepidurallyhalf an hour before shifting in cardiac recovery room. Hemodynamic parameters like Heart rate, systolic and diastolic blood pressure, pulmonary artery pressure were recorder for 72 hours postoperatively. We have compared extubation time in both the groups. Pain was assessed by visual analogue scale (VAS). Any patients with the VAS more than 4 were treated with rescue analgesic. Duration of analgesia and total no. of rescue analgesia were recorded. Duration of stay in cardiac recovery room and in hospital was also recorded.

Observation & Results: We have observed statistically significant difference in hemodynamic parameters between two groups with better stability in TEA group from shifting till next 72 hours. Extubation time was also earlier in TEA group. Mean duration of analgesia and VAS score was also better TEA group. All these led to shorter length of cardiac recovery stay and earlier discharge from the hospital with less complication.

Conclusion: Thoracic epidural analgesia is better than intravenous technique in terms of early extubation, maintaining hemodynamic stability and better postoperative analgesia with reduced length of cardiac recovery and hospital stay.

Key words: Thoracic epidural analgesia, Tramadol, Coronary artery bypass graft surgery

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Introduction

Pain is always subjective perception that cannot be objectively defined satisfactorily. The aim of an anesthesiologist is to render the patient pain free, during intra operative as well as post operative period. Accurate assessment and understanding of pain are vital for providing satisfactory pain control and optimizing recovery. There are various methods for providing post-operative analgesia i.e. intravenous analgesia with various analgesic drugs like opioids, NSAIDs, etc; intrathecal or epidural administration of analgesics or local anaesthetic drug, patient controlled analgesia, nerve blocks & local infiltration etc.

Application of Thoracic Epidural Anaesthesia (TEA) to patients undergoing cardiac surgery during the modern surgical era was initially reported by Hoar et al in 1976¹. Patients receiving TEA had significantly lower postoperative levels of pain mediators compared with control patients. TEA leads to more rapid recovery after CABG, with earlier extubation and shorter stays in intensive care and in the hospital².

Tramadol is an effective and well tolerated opioid analgesic used to reduce pain resulting from surgery, trauma, and also used for the management of chronic pain of malignant or nonmalignant origin. Tramadol appears to produce less constipation and dependence than equianalgesic doses of strong opioids.

Our aim of the study was to compareextubation time, pain relief and post-operative outcome in patients receiving Tramadol via Thoracic epidural versus intravenous method in coronary artery bypass graft surgery.

Aims and Objectives of Study

The aim of this study was to compare pain relief and post-operative outcome in patients receiving Tramadol via Thoracic epidural versus intravenous method in coronary artery bypass graft surgery.

Objectives of the study were to compare,

- 1. Cardiovascular Parameters & incidence of ischemia or arrhythmia
 - 2. Post-operative analgesia & VAS score
- 3. Post-operative outcome such as extubation time, length of stay in cardiac recovery room and hospital
- 4. Any complications related with drugs or technique

Material And Methodology

This was prospective randomized study. Sixty patients aging 40-65 years posted for Cardiac Surgery at "Matsama" Heart Centre, Dhiraj General Hospital during the period of November 2012- June 2014 were selected. Clearance from institutional ethics committee was obtained. Patients were subjected to pre-anesthetic checkup and informed consent was obtained from all the patients.. They were randomly allocated into two groups; group TEA (Thoracic Epidural Analgesia) and Group IVA (Intravenous Analgesia) with 30 patients in each group by chit method.

Inclusion criteria:

Patient who were posted for off pump coronary artery bypass graft surgery (OPCABG)&willing to participate were included in our study.

Exclusion criteria:

- 1. Patient refusal.
- 2. Patients with coagulopathy.
- 3. Patients on potent anti-epileptics, analgesics, anti-platelets, or on anticoagulants.
 - 4. Patients with spine deformity.
- 5. Patients with local skin infections at site of epidural injection.
- 6. Known allergy to the study drugs or local anesthetics.

Preoperative management

Tab. Alprazolam 0.25 mg was given on the night prior to surgery. Patients were asked to restrict fluids and solids by mouth at least six hours before operation. Anesthesia procedure explained and a written informed consent was obtained from them.

After taking patient inside Operation Theatre, multipara monitors were applied and base line respiratory rate, pulse rate, non-invasive blood pressure, SpO₂ and ECG were recorded. Intravenous line was secured with 18G IV line and the patients were started I.V. fluids. Premedication ofInj. Glycopyrrolate 0.2 mg, Inj. Ondansetron 4 mg and Inj. Ranitidine 50 mg ivwas

given.Radial cannulation was done and baseline ABG was taken. Then all other invasive (femoral, PA/CVP) cannulations were done. Arterial pressure monitoring and CVP/PA were started.

In TEA group, the epidural catheter was inserted with catheter tip was kept around T1-T2 level. The blockade require for thoracic surgery is T_1 - T_8 .

All the patients were preoxygenated with $100\% O_2$ for 3 minutes. They were induced with Inj. Fentanyl 5-10 µg/kg, Midazolam 0.05 to 0.1 mg/kg, Vecuronium 0.2 mg/kg i.vand intubated by direct laryngoscopy with appropriate sized Endotracheal tube. Tube was fixed after checking bilateral air entry and maintained with oxygen, Isoflurane, Muscle relaxants (top-ups) and fentanyl-midazolam infusion.

Group IVA (n = 30) received Inj. Tramadol 1 mg/kg iv half an hour before shifting in cardiac recovery room as a post-operative analgesia.

Group TEA (n = 30) received epidural dose of Tramadol 0.5 mg/kg, half an hour before shifting in cardiac recovery room for post-operative analgesia. Total volume required was calculated as per 1 ml for each spinal segment to be blocked.

Intravenous fluids and blood were replaced as per the requirement.

Patients were monitored intraoperative for pulse rate, blood pressure, SpO₂, ECG, PA pressure, Temperature and ETCO₂& other complications.

Post-operative management:

With stable hemodynamic, all patients were transferred to the cardiac recovery room with endotracheal tube in situ and ventilated with SIMV mode initially. Patients were extubated in cardiac recovery once the patient fulfilled following criteria.

Weaning criteria:

- No acute ischemia or new arrhythmia
- · Hemodynamically stable
- · Blood loss < 2ml/kg/hour for first 2 hours
- · Urine output > 0.5 ml/kg/hour

- · Demonstrating signs of awakening from anesthesia
 - · Core temperature 97.2 to 99.8 F

After fulfilling above mentioned criteria patient was weaned off to CPAP mode.

Extubation Criteria:

- · Patient is awake and cooperative (follows verbal commands & moving all four limbs)
 - · Able to lift head for more than 5 sec.
 - · Spontaneous tidal volume > 6ml/kg
 - · Respiratory rate < 30/min
- · ABG obtained in CPAP trial meets the following criteria

pH> 7.35, PCO2 < 45, PO2 > 80 with FIO2 \leq 40

To minimize the complications related to epidural catheter such as infection or malposition, we have removed Epidural catheter after 72 hours. Thereafter, conventional rescue analgesics were given to control pain.

Postoperative monitoring:

All patients of both groups will be monitored for:

- Heart rate (HR).
- Systolic & Diastolic blood pressure (SBP & DBP)
 - Arterial oxygen saturation (SpO₂).
 - Extubation time
 - VAS score
 - Duration of Analgesia
- Total no. of rescue doses of analgesics in first 24 hours
- Total length of cardiac recovery room and hospital stay

Assessment of analgesia

Pain was assessed by visual analogue scale (VAS) immediate post-operatively and every 3 hourly for first 12 hour then 6 hourly till next 72 hours. Any patient with the VAS more than 4 was treated with rescue analgesic Inj. Paracetamol 15 mg/kg i.v.

For visual analogue score, the patient was taught on 10cm scale telling him that 0 (zero) represents "no pain" and 10 represent "worst pain". The patients then mark off on the scale the degree of pain he was suffering.

0	1	2	3	4	5	6	7	8	9	10
No	Mild Pain			Moderate Pain			Severe Pain			
	Good coughing on physiotherapy & no assistance in ambulation		Poor cough Require moderate assistance to ambulate			Unable to cough = Poor Require full assistance to ambulate				

Postoperative first analgesic requirement.

As in cardiac surgery, we can't allow the patients to suffer from pain. So as per the previous studies we have fixed the duration of top-up doses which was 8 hours in IVA and 10 hours in TEA.

Complications

Post-anesthetic side effects or complications, if any reported as:

- Ø Nausea, Vomiting
- Ø Itching
- Ø Respiratory complications (such as atelectasis, pneumothorax, pleural effusion)
 - Ø Accidental dura puncture, Epidural hematoma
 - Ø Backache

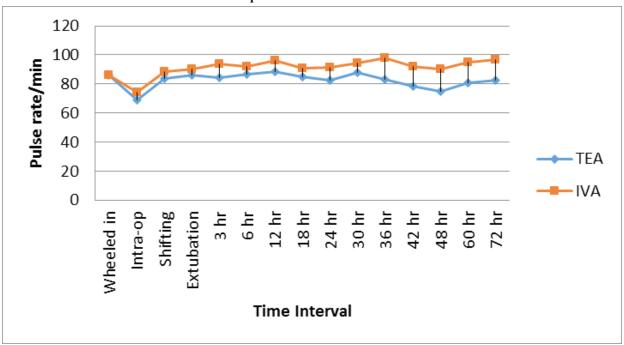
- Ø High Block, Catheter malposition
- Ø Any newer onset of ischemia or arrhythmia
- Ø Neurological injury

Observation & Results

Statistical methods: Data were collected, tabulated, coded then analyzed using GRAPHPAD PRISM computer software version 6.0. Numerical variables were presented as mean & standard deviation (SD) while categorical variables were presented as percent. Data were analyzed with unpaired student – t test. P value < 0.05 was considered significant and <0.001 was considered highly significant.

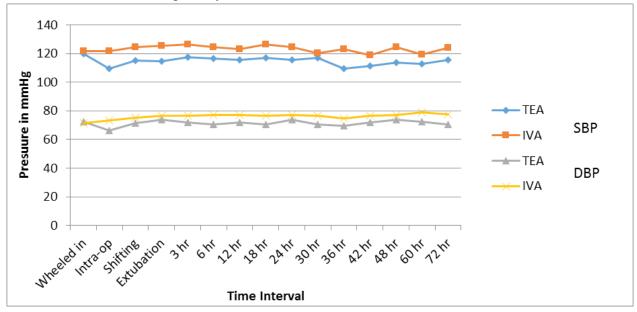
The distribution of patients with respect to age, height, weight and duration of surgery was comparable in both the groups (p value > 0.05).





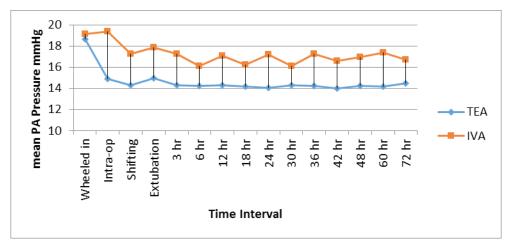
As shown in graph, there was statistically significant difference in pulse rate between the two groups (p value < 0.05). TEA group patients had lower pulse rate and had less pulse rate variation throughout study duration.

Graph 2: Systolic and Diastolic Blood Pressure Variation



As shown in graph, there was statistically significant difference in systolic blood pressure between two groups (p value < 0.05). TEA group patients had lower systolic blood pressure and had less systolic blood pressure variation throughout study duration.

As shown in graph, there was statistically significant difference in diastolic blood pressure between two groups (p value < 0.05).TEA group patients had lower diastolic blood pressure and had less diastolic blood pressure variation throughout study duration.



Graph 3: Mean PA Pressure (mPAP) variation

We had observed statistically significant difference in mean PA Pressure (mPAP) between two groups. (P<0.05) TEA group patients had lower mean PA pressure and had less mean PA pressure variation throughout study duration.

Group TEA Group IVA Event P value Remark SD SD Mean Mean S Extubation Time (in 123.74 1.553 197.6 2.248 < 0.05 minutes)

Table1: Mean extubation time

S= statistically Significant

As shown in table, there was significant difference in mean extubation time with early extubation in TEA group compared to IVA group.

Table 2: Analgesic Profile

Event	Group T	EA	Grou	p IVA	P value	Remark
Event	Mean	SD	Mean	SD	1 value	
VAS score at 1st Top up analgesia	2.133	0.124	2.833	0.136	< 0.05	S
No. of rescue Doses in 1st 24 hours	2.267	0.135	4.443	0.149	< 0.0001	HS
Overall VAS Score in 1st 24 hours	0.412	0.0112	1.862	0.0412	< 0.001	HS

We had observed statistically significant difference in VAS score at 1st top up analgesia between two groups (P<0.001). TEA group had less VAS score at 1st Top up analgesia as compared to IVA group. (P<0.001)

We had observed statistically significant difference in total no. of rescue analgesic doses and overall VAS score in 1st 24 hours between two group (P<0.001). TEA group patients required less rescue analgesic dose compared to IVA. Overall VAS score in 1st 24 hours was also less in \

Table 3: Total Length of Cardiac Recovery stay and Discharge from hospital

Event	Group TEA		Group 1	IVA	P value	Remark
Event	Mean	SD	Mean	SD	rvalue	Kemark
Total length of cardiac recovery stay in hours	83.43	0.62	100.4	1.32	< 0.001	HS
Total length of hospital stay in days	7.367	0.089	8.74	0.1282	<0.001	HS

There was statistically significant difference in cardiac recovery and hospital stay between both groups (p-<0.001) with less stay in TEA group.

In our study, we had observed newer onset of arrhythmias in 13% of patients in TEA group. It was VPCs, while 20% of patients in IVA group had developed newer types of arrhythmias which include 2(6.67%) patients of atrial fibrillation and 4(13.33%) patients of VPCs. Incidence of nausea and vomiting was slightly on higher side in IVA group which was controlled by antiemetic. In Chest X-Ray of postoperative day 1 and day 2, 10% of patients in IVA group had developed pulmonary complication such as 2(6.67%) had mild pleural effusion and 1(3.33%) had left lower lobe collapse. In group TEA, only 1(3.33%) patient had mild pleural effusion.

Discussion

The use of Coronary Artery Bypass Graft (CABG) surgery in the elderly population in the United States has doubled every 5 years since 1985 and in 2003 approximately 5,00,000 cardiac procedures were performed in the US at a cost of around \$9 billion. Thusthe focus of cardiac anaesthesia started shifting in the early 1990's to lower dose opioids, earlier extubation and decreased ICU stay. This came to be labeled as 'Fast Track Cardiac Anaesthesia' (FTCA)³. There are no fixed, accepted definitions in this field but general

consensus accepts the following:

- FTCA is an extubation within 8 hours of the end of surgery. Many major centers, however, aim for extubation 1 4 hour postoperatively.⁴
- There is also the notion of Ultra Fast Track Anaesthesia (UFTA) which refers to extubation of patients in theatre post cardiac surgery.

Application of TEA to patients undergoing cardiac surgery during the modern surgical era was initially reported by Hoar et al in 1976. Subsequently, thoracic epidural anaesthesia and analgesia have been utilized in the intra operative and post operative anesthetic management of patients undergoing cardiac, thoracic and upper abdominal surgeries. 5

Pain may be associated with many interventions, including sternotomy, thoracotomy, and leg-vein harvesting, pericardiotomy, and/or chest tube insertion, among others. Inadequate analgesia and/or an uninhibited stress response during the postoperative period may increase morbidity by causing adverse hemodynamic, metabolic, immunologic, and haemostatic alterations^{6,7}.

TEA lower the pain score, enable earlier extubation, and reduce the incidence of complications, including respiratory system infections, acute renal failure, and acute confusion secondary to intravenous opioid usage^{8,9} and therefore earlier discharges⁸⁻¹². Use of TEA also results in reduced infarct rates during and after surgery in patients with ischemic heart disease¹³⁻¹⁴.

In our study patients in TEA group had lower pulse rate, SBP, DBP and also had less variation compared to IVA group. PA pressure was also less with less variation in TEA group compared to IVA group.Nagwa Ahmed EbrahimMegahedet al. 15 also observed Thoracic epidural analgesia with bupivacaine had better control on hemodynamic changes intraand postoperatively. Chakravarthy et al. 16 observed significant reduction in PA pressure after administration of thoracic epidural in patient planned for aortic valve replacement.

Extubation time is directly dependent on the anesthesia technique implicated and usage of opioids and inhalational anesthetics. Higher use of opioids and anesthetics leads to higher level of sedation. TEA had been associated with lesser sedation level secondary to reduced need of opioids.

In our study, mean extubation time was 123.74 ± 1.55 min in TEA while 197.6 ± 2.25 min in IVA group which was significant (P < 0.05). Length of ICU stay was 79.07 ± 1.17 hours in TEA while in IVA, it was 100.2 ± 1.32 hours which was strongly significant (P<0.001). Duration of discharge from hospital was 7.367 ± 0.089 days in TEA as compare to 8.74 ± 0.1274 days in IVA group. This effect was observed due to reduced need of opioids and inhalational anesthetics in TEA group leads to lower level of sedation. This causes early extubation and reduced length of ICU stay and early discharge from hospital.

Priestly et al.¹⁷ studied use of thoracic epidural to have early extubation and reduce length of hospital stay. They have concluded that TEA leads to faster recovery and early extubation but it has no significant effect on length of hospital stay. Nevriye Salman et al¹⁸ studied use of Thoracic epidural analgesia in CABG. They have observed similar results in terms of extubation time and early discharge from hospital.

Mean duration of analgesia which was calculated as time period from the administration of study drug which was half an hour before shifting till first rescue analgesia was given (VAS \geq 4). It was 597.3 \pm 3.89 minutes in group TEA compared to 435.2 \pm 6.37 minutes in IVA group. VAS score at 1st top-up dose was 2.133 \pm 0.124 in TEA in comparison with 2.833 \pm 0.136 in IVA group.

Mean number of rescue doses in 24 hours was 2.267 \pm 0.135 in TEA group compared to 4.443 \pm 0.149 in IVA group. Overall VAS score in 24 hours was 0.412 \pm 0.011 in TEA group as compared to 1.862 \pm 0.043 in IVA group.In study done by Royse et al. 19, TEA was associated with lower pain scores compared to intravenous morphine, both at rest and during coughing, during the first two postoperative days.

Bloomberg et al.²⁰ observed that TEA increases the epicardial diameter of stenotic vessels along with dilatation of coronary vasculature. Thus, it increases coronary blood flow and reduces the incidence of post operative infarction in CAD patients. In our study, we have not observed any recent changes in ECG except VPCs in TEA group. Mehta Y. et al. also observed similar results in their study.²¹

Conclusion

Thoracic epidural analgesia is better than intravenous technique in terms of maintaining hemodynamic stability,goodpost operative analgesia and better postoperative outcome with reduced length of total hospital stay.

Source of Funding-Self

Conflict of Interest - None

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