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ORIGINAL ARTICLE

A PILOT STUDY OF COMPARISON BETWEEN CONTINUOUS PARAVERTEBRAL BUPIVACAINE INFUSIONS V/S INTRAVENOUS PARACETAMOL INFUSIONS FOR PAIN RELIEF IN PATIENTS UNDERGOING MINI INVASIVE CORONARY ARTERY BYPASS GRAFTING

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ABSTRACT: BACKGROUND: Optimum pain relief following mini invasive CABG is essential for patient comfort and to reduce the incidence of postoperative pulmonary complications. **METHODS:** A randomized clinical trial was conducted on 30 patients scheduled for mini CABG. The patients were randomly divided into two groups. After surgery in group A- paravertebral infusion of local anaesthetics (PVB), bolus dose of 5 ml of 0.25% bupivacaine was injected through the paravertebral catheter in supine position; followed by an infusion of 0.125% bupivacaine at the rate of 0.1 ml/kg/hr, which was continued in the postoperative period. In group B- intravenous paracetamol (IVP), after shifting patient to ICU paracetamol infusion of 10mg/ml is started a 15 ml/hr if patient weight is >50kg. If patient weight is <50 kg infusion started at 0.3ml/kg/hr. Adequacy of analgesia was assessed at rest and during coughing over 48 hours. Analgesic efficacy was assessed using a visual analogue score. **RESULTS:** Pain scores were significantly higher in Group A during the assessment period. ($p<0.01$) as compared to the group B. Forced expiratory volume in one second (FEV_1), arterial oxygen tension (PaO_2) and arterial carbon dioxide tension ($PaCO_2$) showed better results in group A as compared with group B. ventilation time and ICU stay were also less in patients who received paravertebral analgesia. **CONCLUSION:** We conclude that in the early postoperative period, the use of 0.125% bupivacaine infusion through the paravertebral catheter in patients undergoing mini CABG improves pain relief and decrease pulmonary complication.

KEYWORDS: Mini invasive Coronary artery bypasses grafting, Paravertebral catheter, Infusion, Bupivacaine, Paracetamol.

INTRODUCTION: Minimally invasive CABG via mini thoracotomy has revolutionised the field of cardiac surgery as it can be performed through smaller incisions. It offers advantage of early ambulation, better cosmetic appearance with a less noticeable scar, lower infection rates, decrease inflammatory response to surgery and less requirement of blood transfusion as compared to the open procedure.[1] Although this technique is associated with smaller incision, It is regarded as one of the most painful incisions conducted, as the operating surgeon must penetrate and retract several layers of muscle tissue, neurovascular bundles, and other soft tissue

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structures of the thoracic region.[2] It leads to reduced mobility and increase in hormonal and metabolic activity. Worsening of the respiratory mechanics can lead to pulmonary complications, atelectasis, hypoxaemia, cerebrovascular accidents, and delayed wound healing and prolonged hospital stay.[3] Optimum pain relief after thoracotomy is essential if the incidence of atelectasis and postoperative pneumonia is to be reduced.[4,5] Patients must not only be pain free at rest but must also be able to breathe deeply, cough effectively and comply with postoperative physiotherapy.

There have been a number of analgesic techniques used to achieve this end point. For pain management in cardiac surgery our institute protocol is intravenous paracetamol infusion (IVP). Various regional techniques are available to alleviate postoperative pain in minimally invasive surgery.[3,6] Thus, we compared analgesia of continuous intravenous paracetamol(IVP) with continuous paravertebral infusion of local anaesthetics(PVB) with regard to quality of analgesia, complications, and haemodynamic and respiratory parameters in patients undergoing minimal invasive coronary artery bypass grafting (CABG).

MATERIAL AND METHOD: After approval from the institutional review board and obtaining informed consent, 30 patients of either sex undergoing elective minimal invasive CABG between May 2014 to February 2015, were included in the prospective randomised study. Patients randomization were done by computer, either to group A, i.e., IVP (n = 15); or group B, i.e., PVB (n = 15). Patients with left ventricular ejection fraction (LVEF) <35%, anomaly of the vertebral column, receiving heparin and antiplatelet medication within the preceding day, serum creatinine >2.0 mg/dl; serum bilirubin >1.8 mg/dl; aspartate aminotransferase or alanine aminotransferase >1.5 of the upper limit of normal and with significant respiratory disease were excluded from the study. Patients requiring preoperative inotropic support or intra-aortic balloon counter pulsation were also excluded. Pulmonary function tests were performed in all the patients. All the patients were premedicated with iv midazolam 0.05/mg/kg 30 minutes preoperatively. On arrival in the operating room, pulse oxymeter and ECG (lead II and V5) were applied. After securing venous access, radial artery cannulation was performed. External defibrillator pads were applied to the patient. In PVB group (group A), the left paravertebral space was catheterised with a 16G epidural catheter at the T6:T7 level using standard method.[5] Tuhoy needle insered 2.5 cm lateral to the midline in a parasagittal line. A transverse process is typically contacted at a depth of 3 to 4 cm. After the transverse process is contacted, the needle is withdrawn to the skin level and redirected superiorly or inferiorly to "walk off" the transverse process. The ultimate goal is to insert the needle to a depth of 1 cm past the transverse process. A certain loss of resistance to needle advancement often can be felt as the needle passes through the superior costotransverse ligament; then catheter tip was advanced approximately 4 cm beyond the needle tip. A test dose of 3 ml of 2% lidocaine with 1:200000 adrenaline was injected through the catheter in all the patients in supine position to rule out subarachnoid placement of the catheter. All the patients were anaesthetised with midazolam, fentanyl, and sevoflurane in oxygen and air, and muscle relaxation was achieved with vecuronium bromide. Double-lumen endobronchial intubation was performed in all the patients using 37- 41F left-sided Robertshaw type PVC tube. The correct placement of the tube was confirmed by fibreoptic bronchoscopy. Monitoring included a

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continuous two-lead ECG with ST segment analysis, direct arterial pressure, pulmonary artery pressure, temperature, oxygen saturation by pulse oximetry, end-tidal CO_2 and volatile anaesthetic agent, thermodilution cardiac output and derived haemodynamic parameters, arterial blood gases, urine output, activated clotting time. Haemodynamic data including heart rate (HR), mean arterial pressure (MAP), mean pulmonary artery pressure (MPAP), central venous pressure (CVP), and cardiac index (CI) were recorded before incision, after thoracotomy, after revascularization and post-operative. All the patients were prepared and draped as for conventional cardiac surgery, permitting sternotomy, if required. Left sub mammary incision at the level of mid clavicular line 5 -6 cm in length. Inter costal space (ICS) for Incision is selected by chest X-Ray and made in one space above the apex of heart. We do not cut costal cartilage. One lung ventilation started. Special left internal mammary artery (LIMA) retractor was used to elevate upper ribs to facilitate LIMA harvesting. Heparin (1 mg/kg) was administered when dissection of the LIMA started. After LIMA harvesting, LIMA-to-left anterior descending artery (LAD) grafting was performed under direct vision using a stabiliser. Other grafting were also completed under direct vision. Chest tube was inserted in left lower space. Double lumen tube was replaced by single lumen tube. After surgery, patients were transferred to the ICU and extubated whenever they meet the extubation criteria. Bedside pulmonary function tests were performed 2 hours after the removal of chest drainage tubes. All the complications were also noted.

After surgery in group A (PVB Group), bolus dose of 5 ml of 0.25% bupivacaine was injected through the catheter in supine position; followed by an infusion of 0.125% bupivacaine at the rate of 0.1 ml/kg/hr, which was continued in the postoperative period. In group B (IVP Group), after shifting patient to ICU paracetamol infusion 10mg/ml infusion is started at 15 ml/hr if patient weight is > 50kg. If patient weight is <50 kg infusion started a 0.3ml/kg/hr.

After extubation Analgesia was assessed by independent observer at 2,12, 24, 36 and 48 hours using a visual analogue scale (VAS; 0mm = no pain and 100mm = worst pain imaginable) both at rest and during coughing. Patients were familiarized with the scale preoperatively, and postoperative pain was assessed using this scale. In group A, If the patient was in pain a 5 ml bolus of the same infused drug was given and the infusion rate increased by 1ml/h as long as the total infusion rate remained less than 0.2ml/kg/h. If this was not sufficient after 30 minutes a further 5ml bolus of the drug was given; and if after a further 30 minutes the patient was still in pain, intravenous narcotics or NSAID's were instituted. Any episodes of nausea and vomiting, itching, motor block or altered sensation were recorded at the same time as pain scores. The rate of infusion of epidural solution was reduced by 1ml/h if the patient was troubled by side effects as long as there was no significant pain. Pulse rate and arterial pressure measurements were continuously recorded perioperative to allow subsequent analysis of all episodes of hypotension. Interventions for hypotension were not made until the mean blood pressure (MAP) < 70 mmHg. If the MAP decreased to less than 70 mmHg, fluid was given to maintain CVP of 8-10 cm of H_2O and the epidural rate was reduced by 1ml/h. If the MAP < 60 mmHg, epidural rate is reduced further b 1ml/hr and inj noradrenaline stared in the dose of 0.03 to 0.07 mcg/kg/min. Any interventions for hypotension were documented.

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Respiratory rate was recorded hourly. If at any time the patient was found to be difficult to rouse or the respiratory rate decreased to less than 9 breaths/min, the epidural infusion was switched off and the patient was re-assessed. The epidural infusion was restarted only if the respiratory rate was greater than 10 breaths/min and the patient easily roused to command. In this instance, the epidural infusion was restarted at 2ml/h lower than the previous rate. Any such episodes were recorded.

Statistical analysis was performed using SPSS, Version 20.0 (Chicago, IL, USA). Qualitative data were expressed as proportions whereas the quantitative data was expressed as mean±SD. Continuous variables were compared by T-test. The mean value of daily blood glucose was compared between the two groups by means of Independent-sample T-test. Above variables were analysed by means of Chi-square test. The level of significance was accepted at $P<0.05$.

RESULT: Patients in both groups were comparable with regard to demographic data, i.e., age, sex, height weight, no. of graft and surgical time [Table 1].

Pulmonary function parameters, including arterial oxygen tension (PaO_2) (93.8±9.67; 92.74 ± 10.06, P= 0.769), arterial carbon dioxide tension ($PaCO_2$) (35.8±3.81; 36.87 ± 3.05, P= 0.403) and forced expiratory volume in one second (FEV_1) (89.87±7.66; 89.27 ± 6.4, P= 0.817) were also comparable in both the groups pre operatively. Forced expiratory volume in one second (FEV_1) (72.34±5.67; 57±4.7, P<0.0001), arterial oxygen tension (PaO_2) (72.34±5.67; 110.87 ± 15.64, P<0.0001) and arterial carbon dioxide tension ($PaCO_2$) (38.27±4.24; 43.6±5.51, P= 0.006) showed better results in group A as compared with group B [Table 2].

VAS scores, 2 hr (39.6±3.98; 55.6±3.27,P<0.0001),12 hr (40.2±5.01; 57.27±3.74, P<0.0001),24hr (32.54±4.07; 40.2±4.95, P<0.0001), 36hr (29.94±4.63; 36.07±4.67, P=0.001), 48hr(23.8±3.65; 33.34±4.66, P<0.0001) were significantly higher in group B as compared with group A; at rest and with coughing, 2 hr (51.67±4.54; 70.14±6.5, P<0.0001),12 hr (46.07±4.7; 69.47±3.93, P<0.0001),24hr (38.47±2.51; 58.27±4.58, P<0.0001), 36hr (34.87±2.27; 52.07±3.62, P<0.0001), 48hr(31.94±3.2; 48.14±2.8, P<0.0001)) were significantly higher in group B as compared with group A. This value, however, were statistically significant [Tables 3].
Post-operative parameters like ventilation time (167.07±28.1; 169.34±31.56, P= 0.837), Rescue analgesia (0, 2 (13.3%), P=0.464 and hospital stay (6.54±1.07; 5.94±0.97, P= 0.116) were also comparable but and ICU stay (3.27±0.8; 4.6±1.06, P= 0.001) were less in patients who received paravertebral analgesia. [Table 4].

Group	Group A (PVB group) N=15	Group B (IVP group) N=15	P value
Age	57.67±6.78	58.87±6.11	0.614
Gender			
Male	14(93.3%)	11 (73.3%)	0.327
Female	1(6.7%)	4 (26.7%)	0.327
Weight (kg)	65.34±10.73	65.2±7.58	0.969
Height (cm)	158.67±13.48	160.8±10.46	0.632
No.of Graft	2.87 ± 0.83	2.80 ± 0.80	0.816
Surgical time (min)	219.87±19.22	217.14±17.18	0.684

Table 1: Demographic data

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Variable	group A (PVB group)	group B (IVP group)	p value
pre PaO_2	93.8±9.67	92.74±10.06	0.769
pre $PaCO_2$	35.8±3.81	36.87±3.05	0.404
pre FEV_1	89.87±7.66	89.27±6.4	0.817
post PaO_2	153.47±17.97	110.87±15.64	<0.0001
post $PaCO_2$	38.27±4.24	43.6±5.51	0.006
post FEV_1	72.34±5.67	57±4.7	<0.0001

Table 2: Pulmonary function parameter

PaO_2: Values of partial pressure of oxygen, $PaCO_2$: Values of partial pressure of carbon dioxide, FEV_1: forced expiratory volume in first second.

	Group A (PVB group)	Group B (IVP group)	P value
Duration	**VAS Score at rest**		
2hr	39.6±3.98	55.6±3.27	<0.0001
12hr	40.2±5.01	57.27±3.74	<0.0001
24hr	32.54±4.07	40.2±4.95	<0.0001
36hr	29.94±4.63	36.07±4.67	0.001
48hr	23.8±3.65	33.34±4.66	<0.0001
Duration	**VAS Score with cough**		
2hr C	51.67±4.54	70.14±6.5	<0.0001
12hr C	46.07±4.7	69.47±3.93	<0.0001
24hr C	38.47±2.51	58.27±4.58	<0.0001
36hr C	34.87±2.27	52.07±3.62	<0.0001
48hr C	31.94±3.2	48.14±2.8	<0.0001

Table 3: VAS Score

VAS: visual analogue scale.

Group	Group A (PVB group)	Group B (IVP group)	p value
Ventilation time	167.07±28.1	169.34±31.56	0.837
Rescue analgesia	0 (0)	2 (13.3)	0.464
ICU stay	3.27±0.8	4.6±1.06	0.001
Hospital stay (days)	6.54±1.07	5.94±0.97	0.116

Table 4: Post-operative parameters

ICU: intensive care unit.

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DISCUSSION: Treatment of acute post-thoracotomy pain is particularly important not only to keep the patient comfortable but also to minimize pulmonary complications. Severe acute pain after thoracotomy due to retraction, resection, or fracture of ribs, dislocation of costovertebral joints, injury of intercostal nerves, and further irritation of the pleura by chest tubes is a normal response to all these insults.[7]

Sub-optimal management of pain after thoracotomy has major respiratory consequences. Inspiration is limited by pain, which leads to reflex contraction of expiratory muscles, and consecutively leads to decreased functional residual capacity or FRC and hypoxemia. In addition, most patients are extubated early to decrease the risk of respiratory sequelae like pulmonary infection. Deep breathing requires stretching the incision. As this may be extremely painful, patients without adequate analgesia try to prevent stretching of the skin incision by contracting their expiratory muscles, i.e., splinting, thus limiting the stretch on the incision during inspiration. This failure to inspire deeply before a forceful exhalation results in an ineffective cough, which in turn promotes retention of secretions, leading to airway closure and atelectasis, reinforcing the importance of adequate analgesia following thoracotomy to avoid the need for reintubation due to inadequate pulmonary toilet. Diaphragmatic contraction is also impaired.[8,9]

In our institute it is protocol to give heparin in CABG patient preoperatively. So it is risky to give neuroaxial block in this kind of patient. So in routine CABG patient we used to give paracetamol infusion post operatively for pain relief. Paracetamol has both analgesic and antipyretic effects. Although the exact mechanisms of action of paracetamol are still unclear, it is thought to exert its analgesic activity by inhibiting the synthesis of prostaglandins in the CNS (central acting) and peripherally blocking pain impulse generation.[10,11] Paracetamol is detectable in the CSF within minutes after IV administration.[12,13] Unlike NSAIDs, paracetamol is not a peripheral COX inhibitor.[10,14] In addition, it has been proposed that paracetamol has a serotonergic (5-HT) mechanism and a cannabinoid agonism mechanism, which may contribute to its analgesic effect.[15]

Mini invasive CABG has started recently in our institute. PVB is also a well-accepted technique for post thoracotomy pain relief.[16] It is safer and easier to perform than thoracic epidural analgesia(TEA). PVB affects intercostal nerves, ipsilateral sympathetic chain, and posterior rami, which mediate backache from straining of posterior spinal muscles and ligaments. Continuous infusion of local anaesthetic provides effective analgesia, restores respiratory mechanics, and prevents early reduction of pulmonary functions.[17] This type of unilateral analgesia is required in mini invasive CABG. It helps in effective pain control, which can reduce the secretion of epinephrine and create this balance inside the autonomous nervous system.[18] Moreover, subendocardial blood flow and myocardial oxygen supply improve secondary to the sympathetic blockade.[19] It also allows early awakening and extubation and improves pulmonary functions. It has also been shown to be effective in postoperative analgesia after thoracotomy.[20] Hypotension and urinary retention are less frequently associated with PVB Literature search revealed that PVB can be administered safely in patients who have received heparin; however, the timing of catheterisation is important.[21] Moreover, there is least risk of epidural haematoma in the event of conversion to conventional CABG.

In the present study, VAS scores at rest and coughing were lower in the PVB group (statistically significant), and rescue analgesic requirement were lower; Blood gas analysis shows better PaO2 and PaCO2 values in group A after extubation, pulmonary function test values were better maintained in the PVB group during postoperative period, indicating better analgesia. The duration of ventilation was also comparable. Pain relief is better while coughing in PVB group that leads to better co-opeartion for physiotherapy and decrease ICU stay.

Major limitations of the study were the number of patients and lack of control group. In conclusion, PVB appears to be a safe and effective technique for postoperative analgesia after mini invasive CABG and is more effective then iv paracetamol with regard to quality of analgesia. In addition, it may be used safely in patients having recent anticoagulation; and it provides unilateral analgesia, which is required in this surgery.

CONCLUSION: We conclude that in the early postoperative period, the use of 0.125% bupivacaine infusion through the paravertebral catheter in patients undergoing mini CABG provides much better pain relief compared to intravenous paracetamol. It also decrease pulmonary complication and ICU stay.

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