

## EFFECT OF PRE-PROCEDURAL ORAL MELATONIN ON THE LEVEL OF ANXIETY AND HEMODYNAMIC PARAMETERS IN PATIENTS UNDERGOING CARDIAC CORONARY ANGIOGRAPHY

Manjunatha KR<sup>1</sup>, Muralidhara Danappa Patel<sup>1</sup>, Ramesh Kumar N<sup>2</sup>, Bharathi KS<sup>3</sup>

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Corresponding Author:

**Dr. Manjunath KR,**

Email: manjucriticare2001@gmail.com

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<sup>1</sup>Assistant Professor, Department of Cardiac Anaesthesia, Sri Jayadeva Institute of Cardiovascular Sciences and Research, Mysore, Karnataka, India.

<sup>2</sup>Associate Professor, Department of Anesthesia, Sridevi Institute of Medical Sciences and Research, Tumkur, Karnataka, India.

<sup>3</sup>Associate Professor, Department of Cardiac Anaesthesia, Sri Jayadeva Institute of Cardiovascular Sciences and Research, Mysore, Karnataka, India

### Abstract

**Background:** Anxiety is common among patients undergoing coronary angiography. Anxiety in turn will lead to increase in heart rate and blood pressure. Melatonin is a hormone which has anxiolytic effect. **Objectives:** The main aim and objectives of the study is to evaluate the melatonin effect on anxiety and hemodynamic parameters in patients undergoing cardiac angiography. **Materials and Methods:** The present study included 80 patients and divided into two groups each of 40. Group-A patients received melatonin (6 mg) and group-B placebo. The entire patient's demographic data was collected. Before ten minutes of the procedure anxiety levels were noted for both groups. Hemodynamic changes were measured at different time periods. All the data was analyzed by SPSS software. **Results:** Comparison of mean age, distribution of gender, body weight and blood groups between the groups not showed any significant difference. Heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP) and mean arterial pressure (MAP) at basal line not showed any significant difference between the group-A and B. There was a significant difference between the groups in compared HR, SBP, DBP and MAP after 5 min, immediately after completion and 20 min after completion. **Conclusion:** The study results concluded that administration of melatonin before coronary angiography significantly reduce the anxiety and also prevent the changes in hemodynamic parameters.

## INTRODUCTION

Coronary artery diseases are one of the most contributory components of acute cardiac diseases and sudden mortality.<sup>[1]</sup> Early diagnosis of coronary artery diseases can reduce the mortality and increase the survival rate.<sup>[2,3]</sup> There are various diagnostic methods available to diagnose coronary artery diseases. Coronary angiography is usually used to measure coronary lumen shape and plaque characteristics in patients with suspected coronary heart disease at the time of their initial visit.<sup>[4-6]</sup> This invasive method is associated with development of complications which range from mild, moderate to severe. The common complications are anxiety, hypertension, tachycardia, which can lead to permanent damage to cardiac tissue.<sup>[7]</sup> Although there are no absolute contraindications to do coronary angiogram, the mental and physical status can increase the incidence of complications. With this

idea however complications in angiography are common, it can be reduced by pre administration of drugs like sedative hypnotics, CNS depressants and general anesthetics. But use of these drugs is associated with adverse drug reactions and contraindications.<sup>[8]</sup> Melatonin is a hormone synthesized in the pineal gland. Tryptophan is the precursor to synthesis of melatonin. Its secretion depends on light and dark cycle.<sup>[9,10]</sup> Melatonin is an agent which regulate the biological clock. Studies showed that low dose of melatonin can reduce the anxiety and maintain the cardio vascular parameters.<sup>[11]</sup> It is also observed that patients with cardiovascular diseases showed decrease in melatonin levels and impaired circadian rhythms.<sup>[12]</sup> Therefore, the present study aimed to evaluate the effect of pre-procedural oral melatonin on the level of anxiety and hemodynamic parameters in patients undergoing cardiac coronary angiography.

## MATERIALS AND METHODS

**Study Design:** Single blind randomized prospective study.

**Study Settings:** The study was done in department of Cardiology, Sri Jayadeva Institute of Cardiovascular and Research, Mysore, Karnataka.

**Study Period**

**Inclusion Criteria**

- Male and females
- Undergoing coronary angiography

**Exclusion Criteria**

- Recent heart surgery
- Congenital anomalies in heart
- Chronic/uncontrolled diabetic patients

**Groups**

**Group-A:** Melatonin (6 mg)

**Group-B:** Placebo (T. Vit D 3)

**Procedure**

A total of 80 patients were included in the study based on inclusion and exclusion criteria. The selected patients were randomly divided into two groups each of 40. All the patients explained study procedure and informed consent was obtained. Group-A patients received melatonin 6 mg and group-B received T. Vit D3. Ten minutes before the coronary angiography baseline anxiety levels were measured using the state-trait anxiety inventory. Patient's hemodynamic parameters were measured by invasive intraarterial blood pressures and recorded immediately before they entered the Cath Lab, as soon as they were on the bed in the Cath Lab, 5 minutes after the start of coronary angiography. Anxiety levels were measured again immediately and 20 minutes after coronary angiography. All the data were recorded and analyzed.

**Statistical Analysis**

The data was expressed in number, percentage, mean and standard deviation. Statistical Package for Social Sciences (SPSS 20.0) version used for analysis. Un paired t test and Chi square test were applied to find the statistical significance between the groups. p

value less than 0.05 considered statistically significant at 95% confidence interval.

## RESULTS

The study included 80 patients and divided into two groups each of 40 patients. Comparison of mean age (Group-A 54.05 and Group-B 56.20), gender distribution and weight not showed any significant difference between the groups. In both groups maximum number of patients (15) had O +ve group compared to other blood groups. A +ve group subjects are more in group-A (8) compared to group-B (12) [Table 1, 2 and Figure 1]. Comparison of mean heart rate not showed any significant difference between the groups (Group-A 76/minute and Group-B 84/minute) preoperatively. There was a significant ( $p < 0.05$ ) difference of compared heart rate between the groups at on cath lab (Group-A 76/minute and Group-B 86/minute), after 5 min (Group-A 76/minute and Group-B 87/minute), immediate (Group-A 77/minute and Group-B 86/minute) and after 20 (Group-A 77/minute and Group-B 89/minute) min of completion of the procedure when compared group-A with group-B. Increased systolic blood pressure was observed in group-B compared to group-A which showed statistically significant at all the time periods except preoperatively (Group-A 122 mm of Hg & Group-B-138 mm of Hg) ( $p < 0.05$ ). Group-B showed significant increase in diastolic blood pressure compared to group-A (Group-A 75 mm of Hg and Group-B 93 mm of Hg). There was a significant difference observed in mean arterial pressure (MAP) between the group-A and B at different time periods of angiography ( $p < 0.05$ ) [Figure 2-5] (Group-A 87 mm of Hg and Group-B 109 mm of Hg). The study results showed that there is a significant change in heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure compared between group-A and group-B at on the cath lab bed, after 5 min of start, immediate and after 20 min of completion of angiography

**Table 1: Comparison of demographic data between the group-A and group-B**

Demographic data	Group-A (MEAN±SD)	Group-B (MEAN±SD)
Age (Years)	54.05±2.19	56.20±3.19
Weight (kg)	69.05±1.32.	68.66±1.04
Height (cm)	164.97±2.01	165.51±2.04

( $p > 0.05$  no significant difference compared group-A with group-B).

**Table 2: Comparison of blood group distribution between the group-A and group-B**

Blood groups	Group-A		Group-B	
	Number	Percentage (%)	Number	Percentage (%)
A +ve	8	20.00	12	30.00
A -ve	1	2.50	0	0.00
B +ve	12	30.00	10	25.00
B -ve	1	2.50	0	0.00
AB +ve	3	7.50	1	2.50
O +ve	15	37.50	16	40.00
O -ve	0	0.00	1	2.50

( $p > 0.05$  no significant difference compared group-A with group-B).

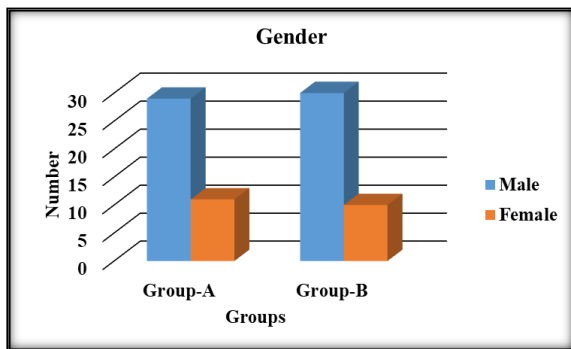


Figure 1: Comparison of gender distribution between the group-A and group-B

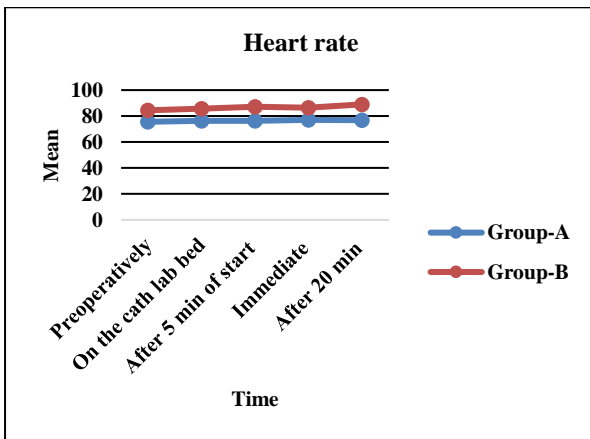


Figure 2: Comparison of heart rate between the group-A and group-B

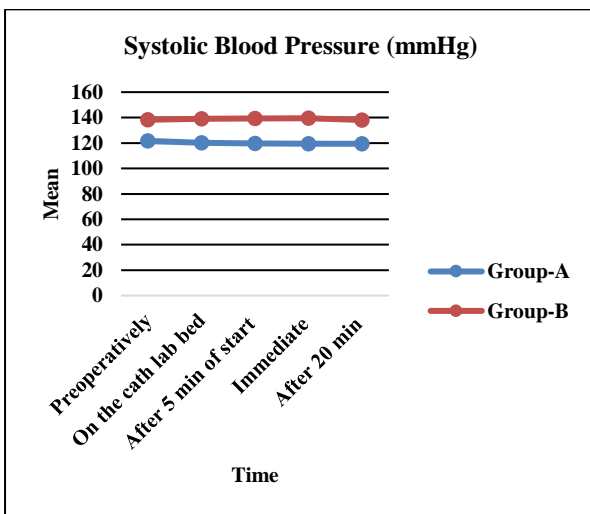


Figure 3: Comparison of mean systolic blood pressure between the group-A and group-B at different time periods

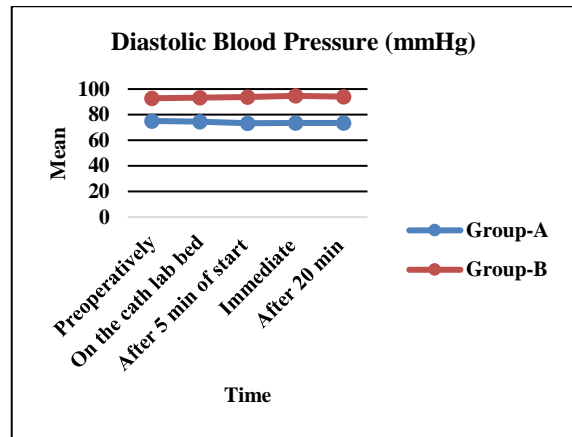


Figure 4: Comparison of diastolic blood pressure between the group-A and group-B at different time periods

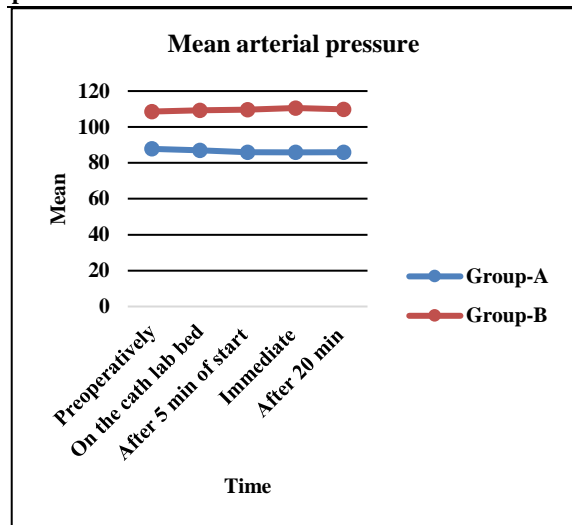


Figure 5: Comparison of mean arterial pressure between the group-A and group-B at different time periods

## DISCUSSION

The present study was done on 80 patients who divided into two groups. Group-A received melatonin and group-B T. Vit D3. Both group's demographic and cardiovascular data was collected and analyzed. The present study showed no significant difference when compared age, gender, weight, height and blood groups between the group-A and B. Mean heart rate, systolic blood pressure, diastolic blood pressure and mean arterial blood pressure not showed any significant difference compared between group-A and B before starting of the procedure. There was a significant change in cardiovascular parameters compared between the group-A and B, during cath lab, at 5 mins of start, immediately and after 20 minutes of completion of the procedure. Melatonin treated group showed significant results compared to placebo group.

Increase in the heart rate, systolic blood pressure, and diastolic blood pressure and mean arterial pressure showed in group-B. This increase was observed at cath lab, after 5 min, immediately and 20 minutes

after the procedure. This hemodynamic changes were significant in group-B compared to group-A. Melatonin administered group showed little changes in heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure compared to placebo group. Padideh G et.al study observed that melatonin administration before coronary angiography significantly prevent the hemodynamic and cardiac injury. In our study results also showed same effect in group-A, which is melatonin administered group.<sup>[13]</sup> Another study done by Stephen et.al, explained the changes in blood pressure, heart rate and mean arterial pressure during the coronary angiography. It was observed that before starting the procedure all the hemodynamic parameters were normal and there is a significant increase during and after 20 min of procedure. These changes may be due to anxiety and activation of cardio vascular system.<sup>[14]</sup> In the present study also showed similar effects. These changes were mainly observed in group-B than group-A. Low dose of melatonin can significant prevent the hemodynamic changes during the coronary angiography. The main limitations of the study are sample size and not estimated melatonin levels in blood.

## CONCLUSION

The study results concluded that pre administration of melatonin significantly reduce the anxiety and changes in hemodynamic indices. Use of low dose melatonin, before angiography can prevent the development of complications and mortality.

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