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EFFECT OF NICORANDIL ON SERUM POTASSIUM LEVELS IN PATIENTS WITH CORONARY ARTERY DISEASE

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ABSTRACT

OBJECTIVE : To study the Effect of Nicorandil on Serum Potassium Levels in Patients with Coronary Artery Disease**.**

METHODOLOGY : 60 patients diagnosed with Coronary Artery Disease, taking Nicorandil were identified. The residual blood was collected and was analysed for serum potassium. The blood samples were collected at the time of admission, third day and followup after 1 month. Quality of Life was analysed by distribution of MINNESOTA LIVING WITH HEART FAILURE QUESTIONNAIRE.

RESULTS : The potassium levels obtained at the admission, third day and follow up was compared and quality of life was assessed.

CONCLUSION : We must be aware of the possible development of increase in potassium levels when patients are placed on Nicorandil therapy. So the serum potassium concentrations should be monitored not only in the initial therapy but also during the full course, as increase in potassium levels is a rare but potential side effect of Nicorandil.

1.0 INTRODUCTION

Nicorandil is an arterial vasodilator having cardioprotective properties via action of ATP sensitive potassium (K^+ATP) channels . It is used as an antianginal agent and coronary vasodilator due to its nitrate- like and K^+ATP channel activator properties. In humans, the nitrate action of nicorandil dilates the large coronary arteries at low plasma concentrations. At high plasma concentrations, nicorandil reduces coronary vascular resistance, which is associated with increased K^+ATP channel opening.

Potassium is a mineral as well as an electrolyte, which means it has an electrical charge. The normal serum potassium level ranges from 3.5-5mmol/L. If the potassium levels in the blood is high, the electrical signal it carries can lead to changes in the heartbeat called arrhythmias. If arrhythmias become severe, they can change the heart's pumping action to such an extent that normal blood flow is interrupted, which can lead to sudden cardiac arrest.

Activation of potassium channels by nicorandil causes expulsion of potassium ions into the extracellular space leading to membrane hyperpolarization, closure of voltage gated calcium channels and finally vasodilation. However, excessive activation of K^+ATP channel, it can expel potassium ions out of the cells and cause Hyperkalemia. In ATP depleted patients with simultaneous use of potassium channel openers can cause channel dysfunction for a prolonged period leading to intractable hyperkalemia.

Coronary Artery Disease can be classified into two : Acute Coronary Syndrome and Stable Angina. Coronary Artery Disease (CAD) can occur due to the deposition of plaques in the innerwall of arteries that supply blood to heart muscles (Atherosclerosis). Thus blood flow gets restricted and can lead to ischemia followed by angina, heart attack and heart failure. The elevated levels of serum potassium are closely associated with the severity of coronary artery lesions.

Since nicorandil is a potassium channel agonist, it should be taken into consideration that there can be changes in serum potassium levels.

2.0 OBJECTIVES

PRIMARY OBJECTIVE :

To find the effect of nicorandil on serum potassium levels in patients with coronary artery disease.

SECONDARY OBJECTIVE :

To determine the beneficial effects of nicorandil in patients with coronary artery disease.

TERTIARY OBJECTIVE :

To assess the quality of life of the patients.

3.0 METHODOLOGY

3.1 STUDY DESIGN :

Prospective Experimental Study.

3.2 STUDY POPULATION :

All patients taking oral Nicorandil 10mg for undergoing treatment of Coronary Artery Disease.

3.3 STUDY CENTER :

The Department of Cardiology, Pushpagiri Medical College Hospital, Thiruvalla, Kerala.

3.4 STUDY PERIOD :

January 2017 – June 2017

3.5 SAMPLE SIZE

60 patients

3.6 STUDY DURATION

6 months

3.7 ELIGIBILITY CRITERIA

INCLUSION CRITERIA

- Patients having Coronary Artery Disease prescribed with Nicorandil 10mg , admitted in the inpatient department, Department of Cardiology, Pushpagiri Medical College, Thiruvalla.
- Those who give consent voluntarily to participate in the study.
- Both male and female above the age of 18

EXCLUSION CRITERIA

- Patients who are not willing to give the consent.
- Patients taking potassium supplements.
- Patients taking drugs causing Hyperkalemia (Penicillin G, ACE inhibitors, Heparin, NSAID).
- Diseases that cause Hyperkalemia (Acute and chronic kidney failure, Hemolytic anaemia, Addisons Disease).
- Patients who are already Hyperkalemic.
- Pregnant and lactating women.
- Paediatric patients.

3.8 STUDY PROCEDURE

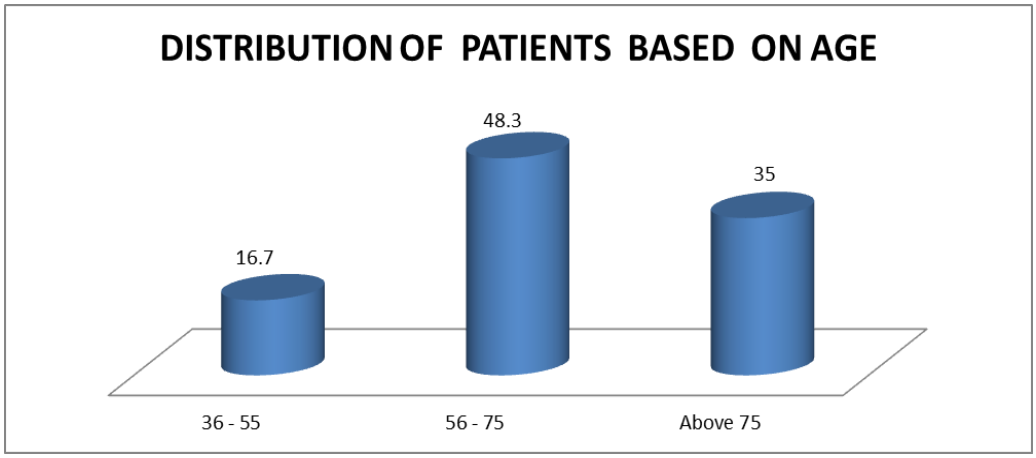
A prospective experimental study was carried out in collaboration with the Department of Cardiology in Pushpagiri Medical College Hospital after getting approval from Institutional

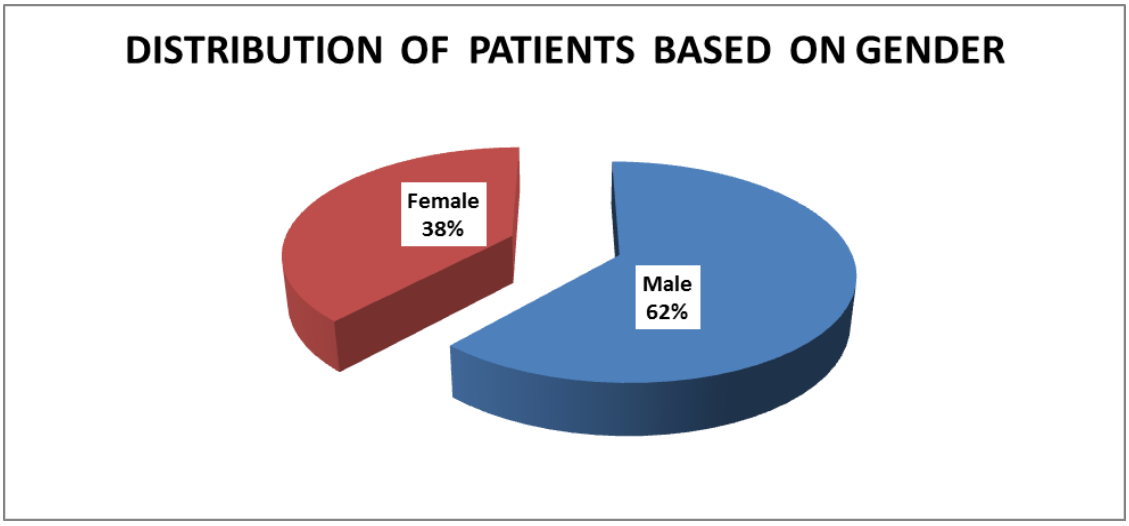
Ethics Committee. All patients were given a brief introduction regarding the study and the confidentiality of data. A written informed consent was obtained from the patients or their care takers, who met the inclusion criteria. Patients diagnosed with Coronary Artery Disease, taking Nicorandil were identified and their hospital record in the department were studied. After obtaining their IP number, name and other demographic details, residual blood (the blood remaining after the blood routine analysis in the lab) is collected from the Biochemistry lab. No financial burden was imposed on the patient. The collected residual blood from the lab was analysed for serum potassium using Semi Autoanalyser in the Pushpagiri College of Pharmacy. Quality of Life was analysed by distribution of MINNESOTA LIVING WITH HEART FAILURE QUESTIONNAIRE.

4.0 STATISTICAL ANALYSIS

SPSS software version 24.

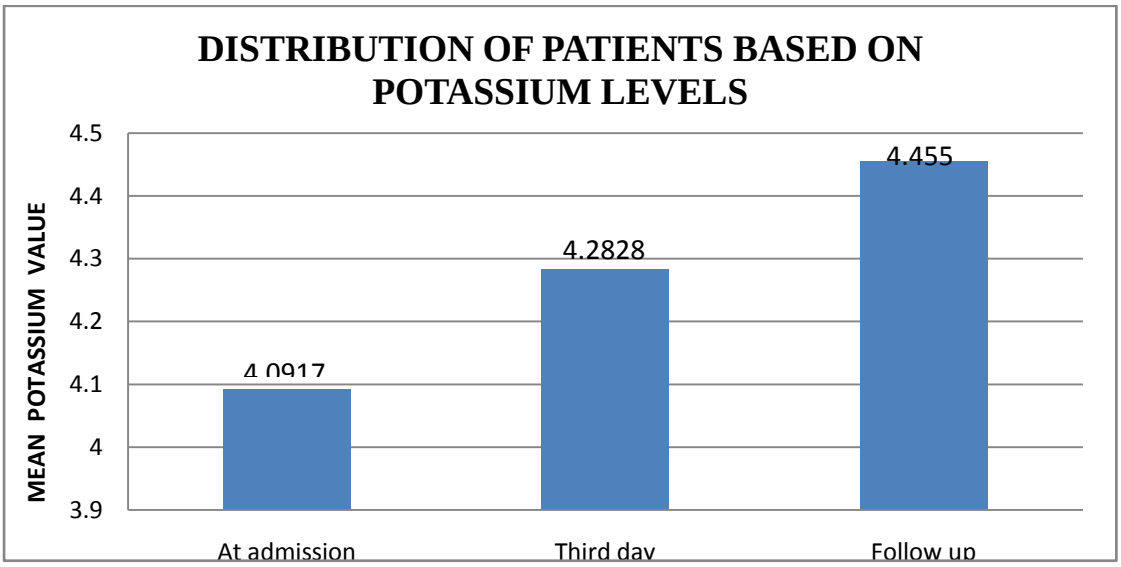
5.0 RESULTS AND DISCUSSION



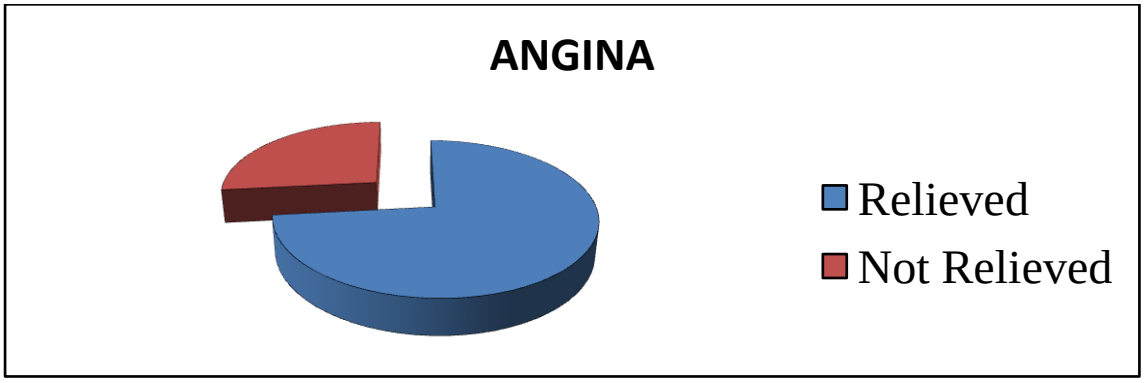


3. DISTRIBUTION OF PATIENTS BASED ON POTASSIUM LEVELS

POTASSIUM LEVELS	MEAN
At admission	4.0917
Third day	4.2828
Follow up	4.4550

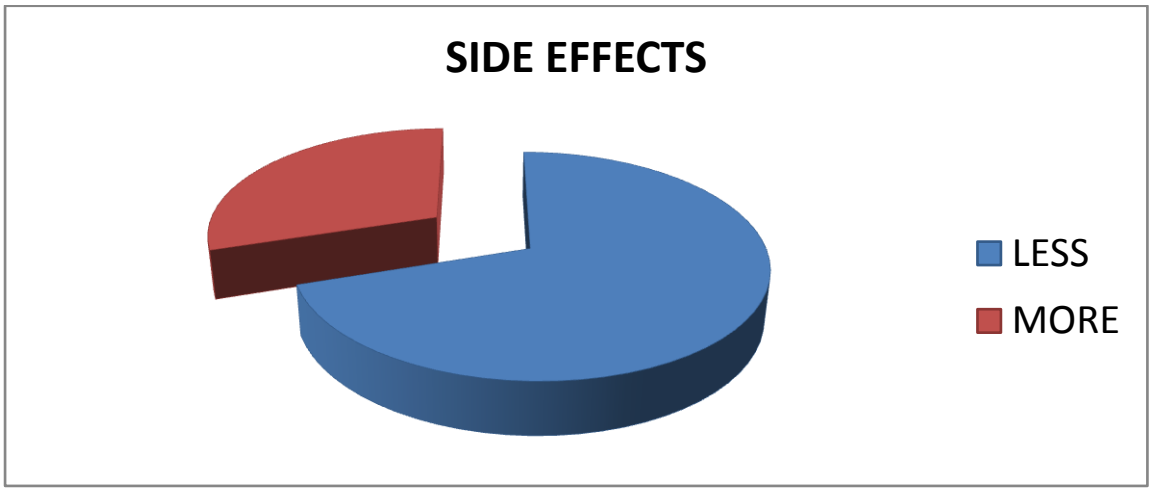


4. DISTRIBUTION OF PATIENTS BASED ON THE BENEFICIAL EFFECT OF NICORANDIL

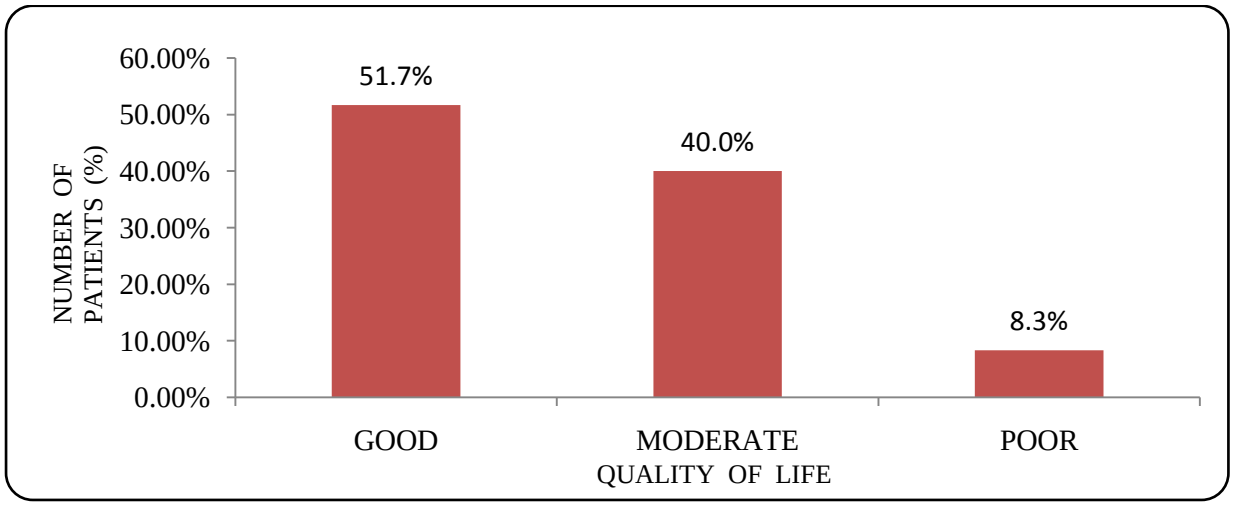


5. DISTRIBUTION OF PATIENTS BASED ON THE BENEFICIAL EFFECT OF NICORANDIL

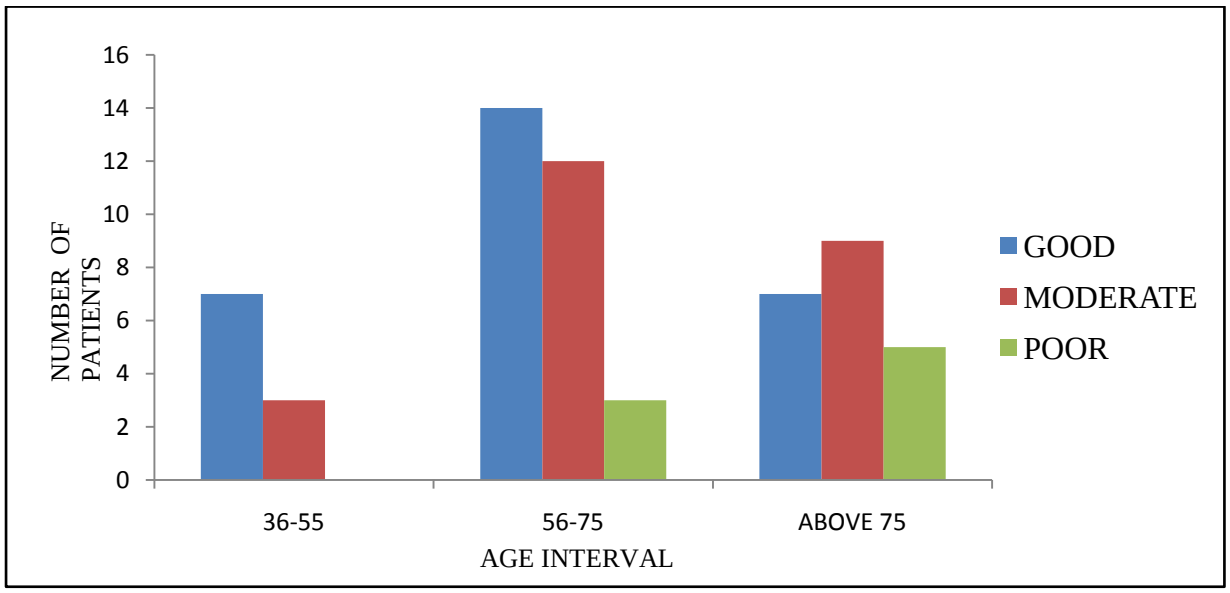
SIDE EFFECTS	FREQUENCY
LESS	42
MORE	18



6. DISTRIBUTION OF PATIENTS BASED ON QUALITY OF LIFE



7. CORRELATION BETWEEN AGE INTERVAL AND QUALITY OF LIFE



6.0 DISCUSSION

A prospective experimental study was conducted in the department of Cardiology, Pushpagiri Medical College, Thiruvalla and Pushpagiri Pharmacy College, Perumthuruthy to find out the effect of nicorandil on serum potassium levels in patients with coronary artery disease. Patients demographic details were collected, residual blood sample were analysed for finding potassium using semi auto analyser. Quality of life was assessed using MINNESOTA LIVING WITH HEART FAILURE QUESTIONNAIRE.

- 60 CAD patients were entrolled in the study,out of which 37 were males and 23 were females.
- The study population includes males than females.
- The study population belonged to the age group of 36-85. Among these, the average age was found to be 68.43 ± 12.25.
- The mean difference in serum potassium levels at admission, third day and follow up were 4.0917, 4.2828 and 4.4550 respectively. The values show that there is a slight increase in serum potassium levels at different time intervals.
- Out of 60 patients, only 8 patients developed Hyperkalemic state (potassium levels above 5mmol/L).
- The incidence of increased serum potassium levels was more in 56-75 age group(48.3%) followed by the age group above 75(35%) and 36-55(16.7%).

- From the study it is clear that Nicorandil is beneficial for the treatment of Coronary artety disease, as it relieves angina with minimal side effects.
- Quality of Life of the patients treated with Nicorandil were found to be Good in 51.7%, Moderate in 40% and poor in 8.3%.

7.0 CONCLUSION

Today, Coronary Artery disease is found to be one of the major heart related disease. Nicorandil, the potassium channel opener is the main choice of drug in the treatment of Coronary artery disease due to its antianginal effect. Our study aims to find the effect of Nicorandil on serum potassium levels, since it is a potassium channel opener. The monitoring of potassium levels in patients were done at the time of admission, third day of nicorandil administration and follow up after one month. Among the 60 patients monitored, only 8 patients developed Hyperkalemic state (potassium levels above 5mmol/L) and most of the remaining showed an increase in serum potassium levels within the range of 3.5-5mmol/L.

Nicorandil is considered to be a safe drug even if it has some common adverse effects such as headache and oral ulcerations. If the patient develop these side effects, then the given dose of nicorandil was reduced to its half and in the case of hyperkalemic state, the drug was replaced by an alternative. The Quality of Life of the patients were monitored using Minnesota Living with Heart Failure Questionnaire and found to be increasing after Nicorandil therapy.

Clinicians must be aware of the possible development of increase in potassium levels when patients are placed on Nicorandil therapy. So the serum potassium concentrations should be monitored not only in the initial therapy but also during the full course, as increase in potassium levels is a rare but potential side effect of Nicorandil. Failure to detect and manage this increase in potassium levels may result in progression to moderate or severe increase in potassium levels that can lead to arrhythmia and cardiac arrest.

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