Research Article

A PROSPECTIVE OBSERVATIONAL STUDY ON MEASURING CLINICAL OUTCOMES OF ENOXAPARIN AND UNFRACTIONATED HEPARIN IN ACUTE CORONARY SYNDROME PATIENTS

Syed Anwar*[1], Anu Nagaraj[1], Jijo Joji[2], Venkatesh[3], Nikhil B[4], Charan C S[5], Hanumanthachar Joshi[6].

[1]Pharm D 5th year students, Sarada Vilas College of Pharmacy, Mysuru, Karnataka, India.

[2]Assistant Professor, Department of Pharmacy Practice, Sarada Vilas College of Pharmacy, Mysuru.

[3]Professor and Head of the Department, Department of Pharmaceutics, Sarada Vilas College of Pharmacy, Mysuru.

[4]Assistant Professor of Cardiology and Interventional Cardiologist, Sri Jayadeva Institute of Cardiovascular Sciences and Research, Mysuru, Karnataka, India.

[5]Associate Professor and Head of the Department, Department of Pharmacy Practice, Sarada Vilas College of Pharmacy, Mysuru.

[6]Principal, Sarada Vilas College of Pharmacy, Mysuru, Karnataka, India.

*Corresponding Author: Syed Anwar, Pharm D 5th year student, Sarada Vilas College of Pharmacy, Krishnamurthy Puram, Mysuru-570004, Karnataka, India.

Email: syedanwartnp786@gmail.com Contact: +917026367869

ABSTRACT:

Introduction: STEMI, NSTEMI and UA are included in Acute Coronary Syndrome. Anticoagulant medications such as enoxaparin and unfractionated heparin lower coagulation activity.

Objectives: To determine the health-related quality of life and pain in the patients treated with enoxaparin and unfractionated heparin.

Methods: A six-month cohort study was conducted at the Sri Jayadeva Institute of Cardiovascular Sciences and Research. Subject enrollment was based on the inclusion of patients above 18 years of age and the exclusion of pregnant and lactating women along with other severe comorbid conditions. Data, including patient demographics, medical history and medication records were collected. Pain and quality of life were assessed using various scales, documented in Microsoft Excel.

Results: A total of 160 patients who met the inclusion criteria were taken. 80 were administered with enoxaparin and 80 were administered with unfractionated heparin. The patients who received enoxaparin showed greater improvement in both the domains of SF-12 questionnaires and also in the visual analogue scale when compared to unfractionated heparin.

Conclusion: Clinical pharmacists play an important role in improving the health-related quality of life for patients with acute coronary syndrome by counseling the patients regarding their condition by educating them about the importance of taking medications regularly and monitoring the patients frequently.

Keywords: Acute coronary syndrome, Enoxaparin, Unfractionated heparin

INTRODUCTION:

The clinical presentation of acute coronary syndromes (ACS) is broad. It ranges from cardiac arrest and electrical or hemodynamic instability with cardiogenic shock (CS) due to ongoing ischemic complications such as severe mitral regurgitation, to patients who are currently not in pain at the time of presentation.

According to ECG alterations, ACS is divided into

1. ST-segment elevation myocardial infarction (STEMI)

2. Non-ST segment elevation myocardial infarction (NSTEMI)

3. Unstable angina

ANTICOAGULANTS:

Anticoagulants are also known as blood thinners. The primary goal of anticoagulant therapy in acute coronary syndrome is to prevent the formation and growth of blood clots.

1. ***Unfractionated heparin***

For many years, unfractionated heparin (UFH) has been the preferred antithrombotic medication.

UFH is administered intravenously. It binds to antithrombin III (AT III) and amplifies its inhibitory impact on Factor Xa. UFH needs to bind to AT and the enzyme to inhibit thrombin (Factor IIa). Heparin does not pass through the placenta or blood-brain barrier which makes it suitable for use as a pregnancy anticoagulant.

2. ***Enoxaparin***

Enoxaparin is a low molecular weight heparin (LMWH). Depolymerizing UFH chemically produces low molecular weight heparin.

There are several benefits over unfractionated heparin such as no platelet activation; better subcutaneous bioavailability (up to 90%); a decreased risk for Heparin-induced thrombocytopenia; and a longer half-life (i.e., twice a day dosing). These advantages make enoxaparin an attractive anticoagulant to be used in acute coronary syndrome management.

MATERIALS AND METHOD:

Study site: The study was conducted at Sri Jayadeva Institute of Cardiovascular Sciences and Research, Mysuru, Karnataka.

Study design: The study was a Prospective observational study.

Study population: We have considered 160 cases in a period of four months.

Study period: The study was carried out for a span of Six months.

Ethical approval: Ethical clearance for the study is obtained from the Institutional Ethical Committee,Sri Jayadeva Institute of Cardiovascular Sciences and Research, Mysuru, Karnataka.

Source of data: All the relevant and necessary data were obtained from

- Medical and medication records of the patient
- Interviewing patient and caretaker
- Communicating with concerned clinicians and healthcare professionals
- Telephonic contact or direct meeting with the patient if needed
- Various questionnaires
- Any other relevant source

STUDY CRITERIA:

Inclusion criteria

- Patients of either gender.
- Patients above 18 years of age.
- Patients diagnosed with ACS.
- Patients who are on enoxaparin medication.
- Patients who are on unfractionated heparin medication.

Exclusion criteria

- Incomplete case sheets.
- Incomplete medical and medication information.
- Pregnant or lactating women.
- Severe comorbid conditions.
- Patients who are not willing to participate in the study by giving informed consent.

STUDY PROCEDURE: The study involved the following steps:

1. Preparation of Informed Consent Form (ICF): An informed consent form was designed in English and the same was translated into the local language i.e., Kannada to acquire consent from patients who enrolled in the study. It is reviewed and approved by the Institutional Ethical Committee. The study was explained in detail to the patient and consent was obtained willingly after the patient had been informed of every aspect of the study. In illiterate patients, the study aspects were explained to the caretakers and consent from their caretakers was obtained.

2. Preparation of data collection form (DCF): A data collection form was suitably designed that included all relevant data of the enrolled patients including demographic details like name, age, gender, IP number, body weight, date of admission and clinical data such as diagnosis, stage of ACS, past medical history, past medication history, history of medication adherence, interventions made, co-morbidities, allergy status, the reason for admission, vitals, lab data, cardiac biomarkers, day

notes, 2D echo and doppler results, ECG and therapeutic data such as name of the drug prescribed, dose of the drug, its frequency, route of administration and duration of administration of the drug.

3. Patient enrollment: Patients who met the study criteria were enrolled in the study after obtaining informed consent. Patients were enrolled in intensive care units, general wards, deluxe wards and semi-deluxe wards
of the cardiology department. Based on their treatment i.e. those who are treated with enoxaparin and unfractionated heparin are enrolled.

4. Data collection: The in-charge authority of the cardiology department was informed and permission was obtained. Data of the patients matching the inclusion criteria were recorded. The patient consent form was given to the patient initially and all the aspects of the study were explained. Signature or thumb impression was obtained from the patients as well as caretakers in the case of illiterate patients. All relevant details of the enrolled patients including the demographics and treatment details were obtained from the patient's medical records and documented in the data collection form. The collected data were entered into the Excel sheet for analysis purposes. SF-12 questionnaire and visual analogue scale were also recorded.

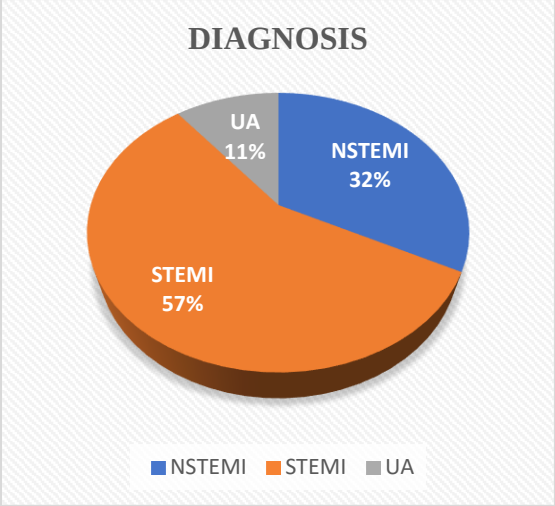
5. Statistical analysis: Data was collected, entered and assembled in Microsoft Office Excel 2021. The entered data was analyzed with the help of Microsoft Office Excel 2021 using descriptive statistical analysis to find out the frequency and percentage of age and gender distribution, quality of life and visual analogue scale. Suitable graphs, tables and charts were added.

RESULTS:

Among 160 patients enrolled in the study, 80 were administered with unfractionated heparin and the other 80 were administered with enoxaparin. 59% were male and 41% were female with the mean average of the population being 59.6 years.

GENDER	FREQUENCY	PERCENTAGE
MALE	94	59%
FEMALE	66	41%

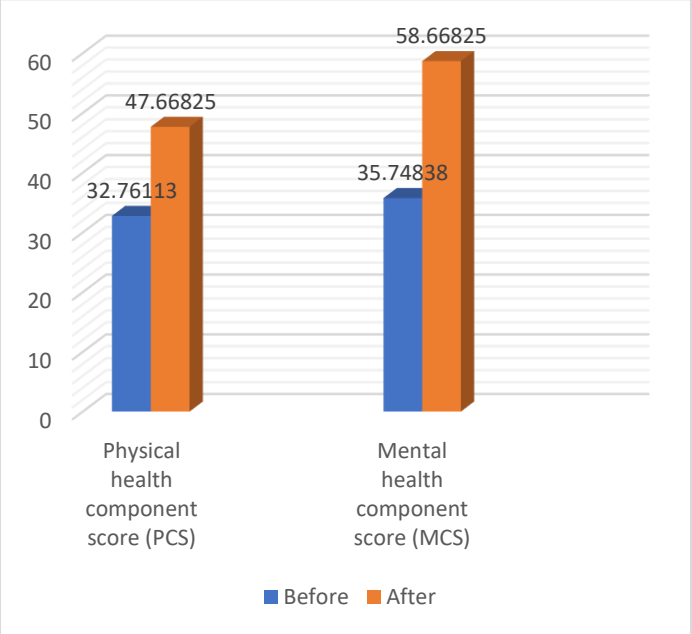
Diagnosis ST-elevated myocardial infarction (STEMI) was found in 91 patients, followed by non-ST-elevated myocardial infarction (NSTEMI) was found in 52 patients and Unstable angina (UA) was found in 17 patients.



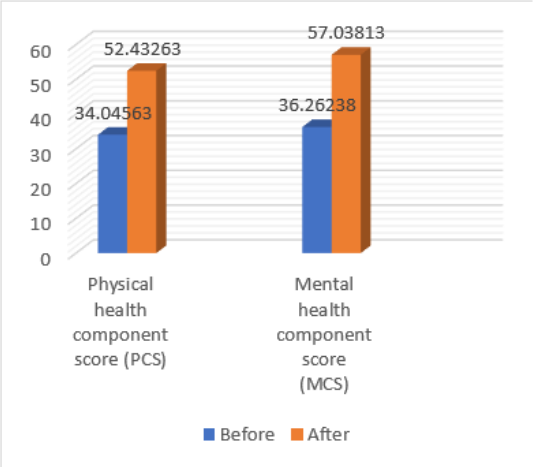
QUALITY OF LIFE

The quality of life was assessed twice using the SF-12 questionnaire, the patients were interviewed during the admission and then followed up after 1 month to calculate the improvement.

The mean quality of life in patients taking unfractionated heparin, the initial Physical health component score (PCS) and Mental health component score (MCS) were 32.76113 and 35.74838 respectively and the final Physical health component score (PCS) and Mental health component score (MCS) were 47.66825 and 58.66825 respectively.



The mean quality of life in patients taking enoxaparin, the initial Physical health component score (PCS) and Mental health component score (MCS) were 34.04563 and 36.26238 respectively and the final Physical health component score (PCS) and Mental health component score (MCS) were 52.43263 and 57.03813 respectively.



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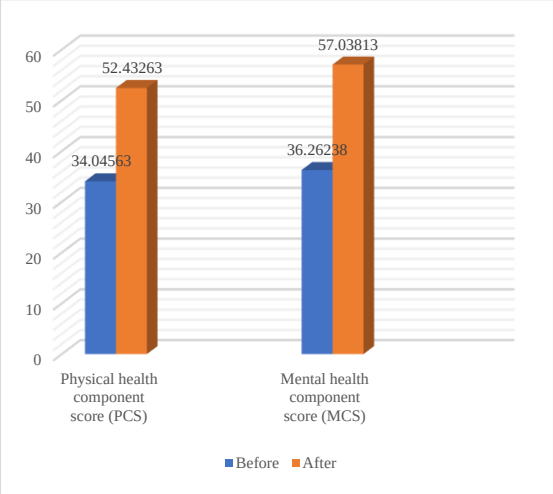
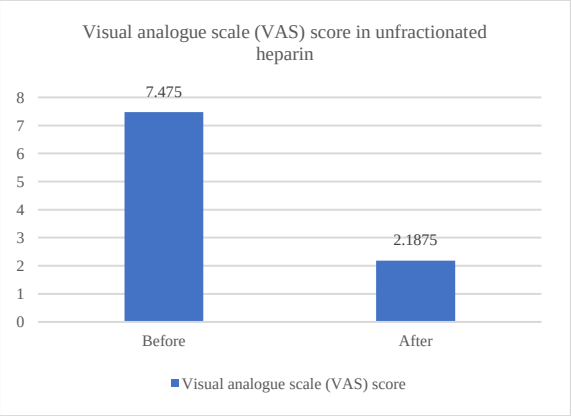
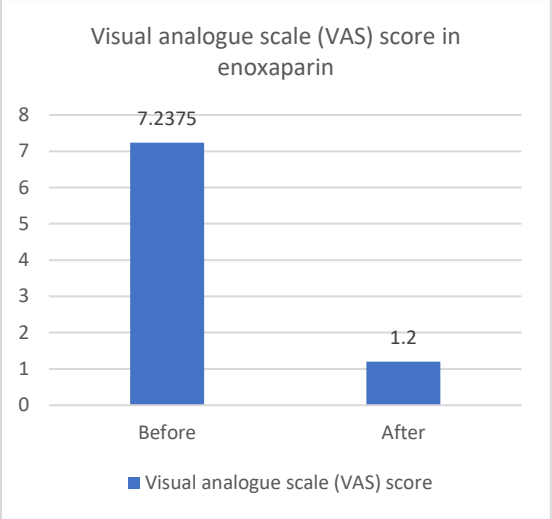


The mean visual analogue scale (VAS) in patients taking unfractionated heparin, the initial and final scores were 7.475 and 2.1875 respectively.



The mean visual analogue scale (VAS) in patients taking enoxaparin, the initial and final scores were 7.2375 and 1.2 respectively.



CONCLUSION:

The patients who received enoxaparin showed greater improvement in both the domains i.e., in the physical health component score (PCS) and mental health component score (MCS) of SF-12 questionnaire and also in the visual analogue scale when compared to unfractionated heparin.

Hence enoxaparin was found to be more effective in the aspect of overall HRQOL (health-related quality of life) and pain when compared to unfractionated heparin in acute coronary syndrome patients.

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