

## A Study on Drug Utilization Pattern in Sickle Cell Disease in a Tertiary Care Hospital

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**ABSTRACT: Background:** Sickle cell disease (SCD) is an inherited disorder caused by a defect in the gene for hemoglobin. Patients can have one defective gene (sickle cell trait) or two defective genes (sickle cell disease) and globally affects 1,00,000 people with 3,000 affected new born each year in US. The management of the symptoms of SCD includes the use of folate supplements, hydroxy urea, analgesics and antibiotics. **Aim:** The aim of the study is to identify the drug utilization pattern in the management of patients with SCD in a tertiary care hospital. **Methods:** This is a prospective study carried out in general medicine and pediatrics ward of the hospital from November 2018 to April 2019. The information was collected from the case notes by the specially designed data collection form which included the demographic data, associated co-morbid conditions and list of prescribed drugs. Data was analyzed using descriptive analysis. **Results:** A total of 76 SCD patients with the mean age of  $12.6 \pm 11.3$  years and 52.6 % of the patients were male. A total of 515 drugs were prescribed with an average of 6.7 drugs per prescription. **Conclusion:** High rate of folic acid is seen in the prescription with SCD patients followed by hydroxyurea and other hematinics. Our study recommends that WHO/ National Center for Biotechnology information reference guide to improve the patient quality of life.

**Keywords:** Sickle Cell Disease, Drug utilization Pattern, Haematinics, Analgesics, Hydroxy urea

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### I. INTRODUCTION

Sickle cell disease (SCD) is an inherited disorder caused by a gene defect of haemoglobin. Patients can have one defective gene (sickle cell trait) or two defective genes (sickle cell disease)<sup>1</sup>. Sickle cell disease is a life-long blood disorder characterized by red blood cells (RBCs) that assume an abnormal, rigid, sickle shape. Sickling decreases the cells' flexibility and results in a risk of various complications. The sickling occurs because of a mutation in the haemoglobin gene. Abnormal haemoglobin, decreases oxygen supply in blood. Due to sickle shape of RBCs it causes difficulty in passing through the small arteries and capillaries and they form clump together to start "logjam". These blocks the blood vessels obstruct blood flow and oxygen to the tissue on the other site of logjam. Because of lack of oxygen and blood supply it cause pain in sickle cell disorder<sup>1</sup>.

In USA, it affects close to 100,000 people with 3000 affected newborns each year, while in the United Kingdom, it is estimated that 12,500 individuals have SCD with an annual birth rate of 300 affected newborns. SCD is said to be the fastest growing serious genetic disorder in the UK and Western Europe<sup>2</sup>. India has the largest concentration of tribal population globally<sup>3</sup>. According to the survey of India 2011, the tribal population of India is 8.6 per cent of the total population which is about 67.8 million people. In Gujarat, More recently very extensive population surveys have been done by the Indian Red Cross Society, Gujarat State Branch where the overall prevalence of sickle cell carriers was 11.37%<sup>4</sup>.

Hydroxyurea therapy is used as the prophylactic management because it lowers the frequency and severity of SCD. It increases the level of HbF, by its cytotoxic effects that can cause erythroid regeneration. Peak plasma level is 1-4 hours after an oral dose. It is used for organ damage, proteinuria, spleen dysfunction, pulmonary hypertension, and hypoxemia<sup>5</sup>. It also useful in the treatment of acute chest syndrome pain crisis, blood transfusion and also decrease the hospitalization<sup>6</sup>. It also prevents the damage of spleen, kidney, lungs and brain damage. The initial dose is 10-15mg/kg/day which can be increased by 5mg/kg/day every 8-12 week up to 35mg/kg/day<sup>7</sup>. Hydroxyurea does not prevent the stroke but they give with a transfusion programme, they prevent the stroke and reduce iron overload from transfusion<sup>8</sup>. Hydroxyurea is approved by the US FDA and lead to decrease the leukocyte count and less inflammation and decrease the haemolysis and vaso-occlusion, it also reduce the number of poorly discomfort dense sickle cell and highly adhesive sickle reticulocyte<sup>9,10</sup>. This study is carried out to assess the drug prescribing pattern in the management of SCD patients in a tertiary hospital at Gujarat.

## II. MATERIAL AND METHODS

**Study design and site:** A prospective observational study was conducted for a period of 6 months at a tertiary care hospital. The study was approved by Institution Ethical Committee of Parul University, Vadodara (Approval number: PUIECHR/PIMSR/00/081734/1809 Dated 30/11/2018).

**Inclusion and exclusion criteria:** All the SCD patients who were willing to give consent were included in the study and demographic details such as age, gender, type of SCD, duration of the hospital stay, laboratory parameters and medications were collected. All patients admitted at psychiatry, surgery and gynecology ward cases were excluded from the study.

**Data analysis:** Data was collected from inpatient departments (IPD) and categorical variable was analyzed by using frequency and percentage. Confidence intervals for the percentage of the users in different formulations, potency, duration, indications was calculated and presented in graphs and tables by using SPSS software (Version 23.0).

## III. RESULTS

### Age-gender distribution:

Seventy six inpatients were recruited for the study, 52.6% were males, and 47.3% were females. It was found that the maximum age group of 11-20 years (42.1%) of the SCD patients and the results showed a significant difference in gender distribution among the different age groups with a p-value of <0.05.

**Table 1: Gender-wise distribution**

Gender	No of patients	Percentage (%)
Female	36	47.37
Male	40	52.63
Total (N)	76	100.00

**Table 2: Age group distribution**

Age (in years)	Number of Patients (n=76)	Percentage (%)
0-10	20	26.32
11-20	32	42.11
21-30	17	22.37
31-40	3	3.95
41-50	1	1.32
51-60	3	3.95

**Types of sickle cell disease:** Out of total 76 patients with SCD, 34 (44.74%) patients found with sickle cell anaemia, followed by 11(14.47%) patients with sickle cell crisis, 10 (13.16%) patients with sickle cell traits, 5 (6.58%) patients with sickle cell syndrome and 16 (21.05%) patients with sickle cell disease.

**Table 3: Types of Sickle Cell Disease**

Disease	No of Patients (n=76)	Percentage (%)
Sickle Cell Anaemia	34	44.74
Sickle Cell Crisis	11	14.47
Sickle Cell Traits	10	13.16
Sickle Cell Syndrome	5	6.58
Sickle Cell Disease	16	21.05

A total of 515 drugs were prescribed with an average of 6.7 drugs per prescription. Analgesics, vitamins and microelements and fluid accounted for 29.7%, 28.5% and 15.6% of the total prescriptions. Out of 153 prescriptions Paracetamol (PCM), Ibuprofen + PCM and followed by Tramadol was also prescribed.

**Table 4: Drugs prescribed among SCD patients prescriptions**

<b>Class of drug</b>	<b>Number of Drugs (%)</b>
Analgesics	153 (29.7)
Antibiotics	61 (11.8)
Vitamins and micronutrients	147 (28.5)
Fluid	80 (15.6)
Others (Hydroxy urea)	74 (14.4)
<b>Total</b>	<b>515</b>

#### **IV. DISCUSSION**

A total 76 patients, the gender ratio of male was found to be 52.63% and for female it was 47.37% during the study period. Although SCD is known to affect males and females equally, significant gender differences in morbidity and mortality have been reported in adults with SCD. Baum et al. reported a striking increase in veno-occlusive after age of 15 years, with a greater rate of pain attacks in males than females. It is believed that men who have the disease experience worse symptoms than women. A possible reason for this is the role of estrogen which help to stimulate the production of nitric oxide, a vasodilator which gives the sickle shaped cells more room to pass through the vessels, preventing blockages which is the cause of sickle cell crisis<sup>6</sup>.

Our study revealed that analgesics were the most prescribed drugs among SCD patients. It was followed by vitamins and micronutrients. Some previous reported that the acute pain episode is the number-one cause of hospital admissions among patients with SCD<sup>11</sup>. The type of analgesics prescribed revealed that narcotics (mild opioids) accounts for 33% of prescribed analgesia. The finding of a reasonable percentage of prescriptions of prescriptions and NSAIDs may suggest that clinicians are adhering to the three step "analgesic ladder" recommended by WHO guidelines.

An assessment of the WHO core prescribing indicators showed that the average number of drugs per prescription was 6.7. This was higher than the WHO standard of 1.6-1.8. This was not unexpected in the management of SCD as prophylactic treatments<sup>12</sup> e.g., anti-malaria prophylaxis, and folic acid may contribute to increased number of drugs per prescription when added to the regimen used in the management of acute painful vaso-occlusive crises.

#### **V. CONCLUSION**

The management of SCD patients conforms to standard guidelines followed by WHO and adhere to improve the patient care. Analgesics were the most commonly prescribed medications, with number of prescriptions for use of hydroxy urea as prophylactic.

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