

## Research Article

# Pentazocine Misuse among Sickle Cell Disease Patients and The Role of Lack of Enforcement of Opioid Dispensing Regulations by Community Pharmacies: A Descriptive Observational Study

Oluomachi Charity Nnachi <sup>1</sup>, Chinedu Obasi Akpa <sup>1</sup>, Favour Ogonna Nwani,<sup>1</sup>  
and Oghenevwoaga Obukohwo Edenya <sup>2</sup>

<sup>1</sup>Department of Haematology, Alex Ekwueme Federal University Teaching Hospital Abakaliki, Abakaliki, Ebonyi State, Nigeria

<sup>2</sup>Department of Chemical Pathology, Alex Ekwueme Federal University Teaching Hospital Abakaliki, Abakaliki, Ebonyi State, Nigeria

Correspondence should be addressed to Oluomachi Charity Nnachi; [obotican@gmail.com](mailto:obotican@gmail.com)

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**Introduction.** Sickle cell disease (SCD) is a chronic disease characterized by debilitating bone pains which commonly necessitate the use of analgesic drugs including opioids and psychotropic substances such as pentazocine which are controlled medicines in Nigeria. Opioid misuse including dependence and addiction is an increasing trend among SCD patients, and it has serious adverse implications on their social, economic, and physical well-being. The role of lack of implementation of existent regulation on the dispensing of opioids by pharmacies has not been adequately investigated. **Objective.** The primary objective of this study is to define the sociodemographic and clinical implications of pentazocine misuse among patients with SCD and to describe the contributions of lack of enforcement of opioid dispensing regulations to this menace. **Materials and Methods.** The study was a descriptive observational study. A 29-item pretested and prevalidated questionnaire was administered to 21 SCD patients with an established history of pentazocine misuse and addiction to establish their demographics, details of opioid use, and their clinical effects. Nine community pharmacies were interviewed to ascertain their knowledge of controlled medicines and their compliance to existent regulations on the dispensation of opioids. **Results.** The median (interquartile range) age of the SCD subjects was 24 years. The majority of subjects (14, 66.7%) had tertiary education. Fifteen (71.4%) of them had a history of pentazocine misuse for over two years. All subjects source pentazocine injection from local pharmacies and patent medicine shops without prescription, while 19.0% get home deliveries. Seventeen (80.9%) of the SCD subjects desired to discontinue the habit; however, inadequate medical support was reported to contribute to their inability to overcome this practice in 14 (54.3%) patients. Most of the local pharmacies/drug shop proprietors are aware of drug laws guiding controlled medicines in Nigeria. However, about 77.9% of pharmacies interviewed retail pentazocine without prescription. A lack of enforcement by the state and federal taskforce was reported to contribute to this practice. **Conclusion.** Pentazocine misuse is a serious problem in patients with SCD. Inadequate medical support and lack of enforcement of regulations on dispensing opioids by community pharmacies are contributors to this menace.

## 1. Introduction

Sickle cell disease (SCD) is an inheritable blood disorder of public health concern in sub-Saharan Africa. It is the most common genetic hematologic disorder in Nigeria [1, 2]. The disease is characterized by severe recurrent bone pains that

commonly prompt the use of analgesic drugs including opioids and psychotropic substances such as pentazocine which are controlled medicines in Nigeria. Pentazocine has a combined analgesic and euphoric effect. It is the main-stay opioid in acute care of moderate to the severe painful crisis in Nigerian sickle cell disease patients [3, 4]. However, a

disturbing aspect of its use is increased self-medication and pentazocine addiction in patients with SCD.

Pentazocine is one of the controlled drugs. In Nigeria, availability and access to controlled medicines are guided by national legislation and policy which ensures the rational use and protection of patients [5]. Pentazocine is among the psychotropic substances listed under Schedule III of nationally controlled drugs. Effective distribution of pentazocine to end users from government-regulated manufacturers or importers is critical to drug control and restriction of accessibility to authorized physician's prescription. Tertiary, secondary, and primary healthcare facilities and authorized community pharmacies are the proper distribution system to patients. These chains of distribution undergo periodic supervision and inspection to ascertain compliance which ensures quality, safety, and adequate documentation as prescribed by regulatory bodies.

The regular unprescribed use of opioids during and in-between pain crises can lead to opioid dependence, which is a complex medical condition that often requires long-term treatment and care. Pentazocine addiction is a growing menace among patients with SCD with serious implications on their social, economic, and physical well-being in addition to the increased healthcare costs of managing associated complications. Some medical complications that increase health costs include associated disability, high risk of hepatitis, and HIV infection when opioids are injected using contaminated injection equipment among others [6–9].

Despite drug control policies in Nigeria, the vulnerability of the SCD population to pentazocine abuse has pursued an alarming trajectory. Previous studies have underpinned major culprit factors fuelling this menace to include limited access to healthcare, poverty, hospital delays, and inadequate pain control in the clinic. However, the role of easy access to pentazocine has not been adequately investigated [4, 10]. Hence, this study seeks to describe the sociodemographic of SCD patients with pentazocine misuse, to identify factors that sustain pentazocine misuse by SCD patients, and to identify factors that facilitate access to the drug in community pharmacies.

## 2. Methodology

**Study design:** this is a descriptive observational study.

**Study area:** this study was conducted at the sickle cell clinic of Alex Ekwueme Federal University Teaching Hospital (AEFUTH), Abakiliki, Ebonyi state, Southeast Nigeria, and community pharmacies in the Abakiliki capital city, Ebonyi state.

**Study population:** the relevant groups to this study include as follows:

- (a) Twenty-one SCD patients with an established history of pentazocine addiction based on criteria for substance use dependence in ICD-10 [11] were consecutively recruited
- (b) Nine community pharmacies randomly selected from different locations of the city

**Study design/tool:** the investigation tool employed in collecting data for this study is questionnaires and oral interviews for clarification. A detailed explanation of the study was provided, and written informed consent was obtained. The SCD patients' relevant data were procured with a pretested and prevalidated self-administered 29 item questionnaire capturing socio-demographic details, hemoglobin phenotype, the pattern of pentazocine abuse, complications, and factors sustaining its use. The community pharmacy questionnaire was pretested among 5 certified hospital pharmacists to construct and content validity. This was administered to nine community pharmacies randomly selected from different locations of the city, and information on pentazocine dispensing and laws regulating its use in Nigeria was ascertained. The supervising pharmacists of the pharmaceutical outlets completed the questionnaires.

Data were analyzed using the Statistical Package for Social Sciences (SPSS), version 16, Chicago, USA. Descriptive analysis was expressed as frequencies and percentages.

Ethical approval was obtained from AEFUTH Research and Ethics committee (REC PROTOCOL NUMBER 17/12/2020–10/02/2021).

## 3. Results

**3.1. Sociodemographic Parameters of Participants.** A total of 21 SCD subjects participated in the study. The median age of the study subjects was 24 years with a female to male ratio of 2.5:1. The majority of subjects (14, 66.7%) had a tertiary level of education. Seventeen subjects (80.9%) were dependents (students/unemployed) (Table 1).

**3.2. Participants' Details on Pentazocine Abuse.** The majority of participants (15, 71.4%) had self-administered pentazocine for more than 2 years. About 52% patients took pentazocine daily, and 14% patients took as much as 150 mg per time. Knowledge of self-medication was first acquired at home through a nearby health worker/parent by 42.8%, while 33.3% and 19% were via treatment from pharmacy/chemist shop and fellow SCD friends, respectively. All procured pentazocine without prescription from; pharmacy outlets (57.1%), chemists (14.2%), and open market (9.5%), while 19.0% got home deliveries. Intramuscular injection (90.4%) is the preferred route, and the buttocks are the most preferred site (71.4%). Abscesses (42.8%) and chronic ulcers (33.3%) were the most frequent complications associated with its use (Table 2).

**3.3. Factors Sustaining Pentazocine Misuse.** Unhindered access to pentazocine (76.1%), lack of funds to visit the hospital (38%), and encouragement by a fellow SCD patient (38%) account for the majority of circumstances necessitating its self-use. Some (14.2%) acquire pentazocine on credit to pay when buoyant, while 52.3% get their pain

TABLE 1: Sociodemographic parameters of the SCD participants.

Variables	N	%
<i>Age (years)</i>		
15–19	3	14.2
20–25	11	52.3
26–30	4	19.0
>30	3	14.2
Median (IQR)	24 (years)	
<i>Sex</i>		
Male	6	28.6
Female	15	71.4
<i>Marital status</i>		
Single	20	95.2
Married	1	4.8
<i>Educational status</i>		
Secondary	7	33.3
Tertiary	14	66.7
<i>Occupation</i>		
Students/unemployed	17	80.9
Healthcare worker	2	9.5
Artisan	2	9.5
Civil servant	1	4.7

relieved with pentazocine only which is cheap with a quick onset of action. About 80% admit to being aware of being addicted and want to stop but are unable to due to failed medical consultation (58.3%) and an irresistible urge to continue (52.3%) (Table 3).

**3.4. Pharmaceutical Outlets’ Report on Pentazocine Dispensing and Laws Guiding It.** All the pharmacy outlets that participated in the study were duly registered and licensed. Most (8, 88.8%) were aware of drug laws guiding controlled medicines in Nigeria. All the participating pharmacies knew that pentazocine should strictly be dispensed on prescription by a physician, but only 1 (11.1%) dispenses it on prescription only. Reasons given for dispensing without prescription were that the buyer is a health worker (8, 88.8%); they feel pity for the patients’ pain (5, 55.5%) or familiarity with the customer (3, 33.3%). The majority of pharmacies procure their pentazocine from government unauthorized distributors (bigger pharmaceuticals 66.6% and open market 11.1%). The majority (7, 77.9%) gave a poor rating to the state and federal task force regulation on pentazocine retail and monitoring. Corruption (100%), lack of government will to empower enforcement of laws (88.8%), and nonprofessionals in the drug business (77.9%) were reasons for this rating (Table 4).

**4. Discussion**

Pentazocine dependence has been notable with prolonged use, and its propensity for addiction has loudened calls on the need to draft actionable protocols for opioid use in sickle cell patients to mitigate this burden.

In this study, the median age of SCA subjects with pentazocine abuse was 24 years with a female to male ratio of 2.5:1. This is consistent with other studies conducted in Nigeria [4, 8, 12]. Sickle cell disease is a chronic and

TABLE 2: Participants’ details on pentazocine abuse.

	Frequency	Percentage
<i>Duration of self-pentazocine use (years)</i>		
<1	1	4.8
1-2	5	23.8
>2	15	71.4
<i>Frequency of pentazocine use</i>		
Daily	11	52.3
At least once/week	3	14.2
At least once/month	4	19.0
Only during painful crises	3	14.2
<i>Usual dose per time (milligram)</i>		
30–60 mg	2	9.5
90–150 mg	16	76.1
>150 mg	3	14.2
Dose increment with time	20	95.2
<i>First knowledge of self-use</i>		
Fellow SCD friend taught me	4	19.0
At home by a nearby health worker/parent	9	42.8
During hospital admission for pain crisis	1	4.7
Treatment from pharmacy/chemist shop	7	33.3
<i>Procurement of pentazocine *</i>		
Home delivery	4	19.0
Open market	2	9.5
Chemist/patient medicine shops	3	14.2
Community pharmacy outlets	12	57.1
Requires prescription	2	9.5
<i>Route of administration</i>		
Intravenous	2	9.5
Intramuscular	19	90.5
<i>Injection sites</i>		
Buttocks	15	71.4
Thigh	7	33.3
Arm	5	23.8
Reuses/shares needles	4	19.0
<i>Complications of pentazocine use *</i>		
Chronic ulcers	7	33.3
Healed scars	2	9.5
Abscess	9	42.8
Disabilities	2	9.5
Ankylosis	2	9.5
Leg swelling/induration	5	23.8
Sedation	5	23.8

\*Multiple answers.

potentially debilitating disease, and being complicated by drug addiction in the prime of youthfulness is indubitably a huge societal burden. The greater number of females may be attributable to the fact that women exhibit greater pain sensitivity and reduced pain inhibition compared to men [13]. This is also disadvantageous to them because it increases the tendency for singlehood among affected females as acknowledged in a case study by Akpan et al. [9]. Similar with previous studies, a majority of the subjects had tertiary education and were students or unemployed [4, 10]. This level of literacy can be harnessed to curb this menace through the tool of counseling and medical/family support.

TABLE 3: Factors sustaining pentazocine misuse.

Variables	Frequency	Percentage
<i>Circumstances that necessitated self - use of pentazocine *</i>		
Shame of repeated hospital visits for pain crises	7	33.3
Unsatisfactory hospital care	1	4.7
Lack of funds to visit hospital	8	38.0
My caregiver treats me at home via a nearby health worker	10	47.6
Fellow SCD patient encourages me to use it	8	38.0
I have unhindered access to it from the pharmacy	16	76.1
<i>Source of fund to procure pentazocine *</i>		
Out of pocket	4	19.0
Caregivers/friends	17	80.9
Buy on credit	3	14.2
Begging	8	38.0
Stealing	7	33.3
Requires current prescription by a doctor to buy it	2	9.5
Gets pain relieve with other analgesia without pentazocine	11	52.3
<i>Pentazocine is preferred to other analgesics because *</i>		
It helps me to sleep	2	9.5
It is cheap and relieves pain fast	11	52.3
It prevents pain	3	14.2
I like the feeling	5	23.8
Adequate family/financial support for illness	15	71.4
Aware of being addicted to pentazocine	17	80.9
Desire to stop misuse of pentazocine	17	80.9
<i>Reasons for inability to stop *</i>		
Medical consultation did not help	14	66.7
Irresistible urge to take it	11	52.3
cannot fund hospital care	6	28.6
I have pains all the time	3	14.2
Feels sick without it	2	9.5

\*Multiple answers.

TABLE 4: Pharmaceutical outlets' report on pentazocine dispensing and laws guiding it.

Variables	Frequency	Percentage
Pharmacy outlet registered and supervised by a licensed pharmacist	9	100
Adequate knowledge of controlled medicine use in Nigeria and laws guiding dispensing them	8	88.8
Aware that pentazocine is a controlled drug	9	100
Aware that pentazocine can only be dispensed with authorized prescription	9	100
<i>Retails pentazocine on prescription</i>		
Always	1	11.1
Not always	7	77.8
No response	1	11.1
<i>Reasons for retailing pentazocine without prescription *</i>		
It is a health worker	8	88.8
Pity for patients in pain	5	55.5
Familiar with the patient	3	33.3
<i>Sources of pentazocine supply</i>		
Open market	1	11.1
Bigger pharmaceutical companies	6	66.6
Authorized government agent	2	22.2
<i>Rating effectiveness of state and federal task force on pentazocine regulation</i>		
Fair	2	22.2
Poor	7	77.8
<i>Reasons for your rating</i>		
Ineffective enforcement of existing laws	8	88.8
Loose control system	7	77.7
Nonhealth professional in drug business	7	77.7
Corruption/greed	9	100.0

Almost all of the SCD participants admitted to the need for pentazocine dose increment with time. They self-administered unacceptably large doses of pentazocine per time. Such craving was also reported in the work of Adewoyin et al. [4]. This is tolerance at play and should get any discerning clinician alarmed on the imminence of addiction.

This study shows that most of the SCD participants took pentazocine intramuscularly as they might not have had the skill and precision for intravenous injection. In agreement with previous studies, the commonest sites of injection were the buttocks followed by the thighs and arms [2, 14, 15]. A thorough physical examination including the buttocks and thighs during clinical consultations could alert the physician to the tale-tale signs of pentazocine misuse.

The notable complications of pentazocine abuse in this study were abscesses, chronic ulcers, and healed scars at the sites of injection [2, 9, 16–18]. These complications might have resulted from the chronic precipitation of acidic pentazocine with repeated injection at the same site. The sites sometimes get infected making healing more difficult and scarring inevitable. About 19% of study participants admitted to the reuse/sharing of needles. This increases the risk of bacterial infection, the transmission of HIV/AIDS, and virus Hepatitis.

In most cases, the first knowledge of self-medication with pentazocine was acquired at home through a nearby health worker or while on treatment in a pharmacy or patent medicine store. In a few cases, fellow sickle cell disease patients were implicated. This shows that health workers/pharmacists are complicit in the escalation of this menace and have a huge role to play in tackling it. Several studies have reported that sickle cell disease cases with pentazocine abuse were more common in those engaged in healthcare-related roles compared to controls [3, 4]. Some of these health workers were not professionally trained and do not understand the enormous consequences of their actions.

This study revealed that 90.4% of the SCD subjects procured pentazocine without the need for a doctor's prescription. The procurement was mostly from community pharmacy outlets; other sources included patent medicine stores, open markets, and sometimes, home deliveries. Unhindered access to pentazocine from the pharmacy, home treatment by a nearby health worker, and encouragement from fellow sickle cell disease patients accounted for the commonest factors that sustain pentazocine misuse. Community pharmacies should be sensitized on the need to stop dispensing pentazocine over-the-counter without authorized prescriptions. Sickle cell disease patients should be counselled on the dangers of encouraging one another to indulge in self-medication. Engaging them through their clubs/organization meetings and non-Governmental agencies will be helpful. Caregivers should be educated on the bane of home treatment of sickle cell disease patients by health workers oblivious to the tenets of sickle cell disease management. They must be enlightened on the need for the hospital rather than the home management of these patients during severe painful crises when approved over-the-counter medications are not effective in pain control. Moreover, this study shows that 71.4% of the SCD

participants have adequate family and financial support to justify hospital management.

Only 4.8% of participants complained of unsatisfactory hospital care as a reason for self-medication with pentazocine contrary to previous studies [4]. It could be that with advancements in knowledge of pain management, patients now have a better outcome than previously thought. About 52.3% of the subjects admitted to get pain relief with other analgesic drugs without pentazocine. This must be explored in a balanced protocol of pain management to minimize pentazocine dependence. Most subjects preferred pentazocine because it is cheap and fast-acting. Paracetamol is even cheaper and also fast-acting, albeit less potent in analgesic effect. Most of the SCD subjects are aware of their addiction to pentazocine and desire to stop it but have an irresistible urge to continue. Unfortunately, medical consultation did not help them [4]. The neuropsychiatrists and psychologists must recognize this challenge. They need to be well equipped to cope with the demands of rehabilitating these patients in collaboration with haematologists.

Our study revealed that all the pharmacy outlets approached in this study were duly registered in Nigeria and supervised by licensed pharmacists. A vast majority had adequate knowledge of controlled medicine use in Nigeria and laws guiding dispensing them. But only a few always retailed pentazocine on prescription. The statistics here show that though pentazocine is a controlled drug, it is being accessed indiscriminately. Most of the pharmacies claim that they retailed it without prescription out of pity for patients, familiarity with the patients, and at other times because the buyer is a health worker. These reasons are unacceptable as they are borne out of ignorance of the fact that they make the patients more harmful than good. The pharmacies must avoid retailing the drug without a doctor's prescription, even to health workers with dubious tendencies.

In this study, the majority of the pharmaceutical outlets rated the effectiveness of the state and federal task force on the pentazocine regulation poorly. They, however, admitted that the laws regulating pentazocine use were adequate, but corruption, greed, loose control system, and nonhealth professionals in the drug business were the major culprits for illicit use. Only 22.2% of the pentazocine supply to the pharmacies were from authorized government agents. This creates room for traders in open markets and bigger pharmaceutical companies to control the supply without adherence to the laws. These people are driven by pecuniary interest and may not understand the dangers of their practice.

Pentazocine is in Schedule III of the list of psychotropic substances and precursor chemicals currently approved by the International Narcotics Control Board (INCB) for use in Nigeria under the 1971 convention [5]. In Nigeria, the control, availability, and access to psychotropic substances and other controlled medicines are guided strictly by international conventions and other local legislations. Indeed, the extant laws are adequate, but the enforcement is weak. The National Agency for Food and Drug Administration Control (NAFDAC) is the body saddled with the responsibility of enforcing the provisions of these conventions and legislations. This includes the regulation of importations, manufacture, distribution, warehousing, sales, and use of controlled drugs [10]. The enforcement has been an

uphill task frustrated by corruption involving stakeholders as seen in this study. To surmount uncontrolled access to pentazocine by SCD patients, the government must develop a strong will to enforce the extant laws to achieve the objectives of the National Policy for Controlled medicines (NPCM). The target is to establish a robust and efficient supply chain system for controlled medicines, create a link between a pharmacy and a prescriber with adequate documentation of the number of drugs consumed, and implement a monitoring and evaluation framework for this policy.

#### 4.1. Limitations of the Study

- (1) The small number of sickle cell patients and pharmacies studied may limit the power of generalizing the outcome of this study
- (2) Owners of the community pharmacies were reluctant to provide relevant information
- (3) The SCD patients were reluctant to provide information on sources and use of pentazocine for the fear of restricting their access to it

## 5. Conclusion

Pentazocine misuse is a serious problem in patients with SCD. Inadequate medical support and lack of enforcement of regulations on dispensing of opioids by community pharmacies are contributors to this menace. Monitoring by the regulatory authorities is weak due to corruption. Higher level professionalism among pharmacists and government support for the regulatory task force is needed. Pentazocine supply via unauthorized vendors should be stopped. Con-dign punishment must be meted out to defaulters under the law to sanitize the system. Multidisciplinary approach by psychologists, psychiatrists, and haematologists is needed in management of these patients. Civil society should create a network of support and education for patients with SCD, caregivers, and family members. All these strategies will ensure the entrenchment of good pentazocine dispensing practices, restriction of access for unauthorized use and good health seeking behaviour in patients with SCD.

## Data Availability

The data used to support this study are available from the corresponding author upon request.

## Conflicts of Interest

The authors declare no conflicts of interest.

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