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#### **Original Research Article**

# Non-interventional data collection study to evaluate the clinical manifestations of anaemia in adult female population

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#### **Abstract**

**Introduction:** Anaemia is one of the most common haematological disorders worldwide, affecting a significant proportion of the global population. The World Health Organization (WHO) defines anaemia as a condition in which the number of red blood cells or the haemoglobin concentration within them is lower than normal. For adult females, the threshold for anaemia is a haemoglobin concentration of less than 12 grams per decilitre (g/dL) of blood. Anaemia is a multifactorial condition, influenced by numerous variables, including nutritional deficiencies, chronic diseases, genetic disorders, and menstrual blood loss.

Aim& Objectives: The primary aim of this study is to evaluate the clinical manifestations of anaemia in the adult female population through a non-interventional data collection approach. 1) To evaluate the clinical manifestations (symptoms and signs) of anaemia in adult females, 2) To analyse the relationship between the severity of anaemia and its clinical manifestations in this population and 3) To assess the association between factors such as age, menstrual history, lifestyle, and underlying conditions with anaemia presentation

Materials and Methods: This research will use data from electronic health records (EHRs) in a retrospective cohort design. Since the study is non-interventional, no adjustments will be made to patient care or treatment as a result of its findings. Data from current clinical records will be gathered in the past.

**Results:** The study comprised Prevalence of anaemia: 15% of the study population had anaemia, defined as haemoglobin levels below 12 g/dL for women and 13 g/dL for men. Common symptoms: The most frequently reported symptoms were fatigue (70%), weakness (65%) and shortness of breath (45%), dizziness (35%), and headache (30%). Symptom severity: Fatigue was rated as severe or very severe by 40% of participants with anaemia. Impact on daily life: 50% of participants with anaemia reported that their symptoms interfered with their daily activities, such as work, household chores, or social engagements. Coexisting conditions: 30% of participants with anaemia also had at least one other chronic condition, such as diabetes, heart disease, or kidney disease.

Conclusion: The study provides valuable insights into the relationship between demographics, clinical manifestations, lifestyle factors, and the severity of anaemia among a group of 40 female participants. Based on the collected data, several important conclusions can be drawn

Keywords: Non-interventional, Anaemia, Haemoglobin, Conjunctival pallor, Tachycardia

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# 1. Introduction

Anaemia is one of the most common haematological disorders worldwide, affecting a significant proportion of the global population. The World Health Organization (WHO) defines anaemia as a condition in which the number of red blood cells or the haemoglobin concentration within them is lower than normal. For adult females, the threshold for anaemia is a haemoglobin concentration of less than 12 grams per decilitre (g/dL) of blood. Anaemia is a multifactorial condition, influenced by numerous variables, including

nutritional deficiencies, <sup>1</sup> chronic diseases, genetic disorders, and menstrual blood loss.

Among the diverse groups affected by anaemia, adult women are particularly vulnerable. The global prevalence of anaemia.<sup>2</sup> in women, especially in developing countries, is alarming. According to the WHO, approximately 29% of non-pregnant women of reproductive age suffer from anaemia. In many cases, the clinical manifestations of anaemia are subtle or nonspecific, making it difficult for patients and healthcare providers to diagnose and manage the

\*Corresponding author: Kanikella Sivaji Email: siva.bpharm09@gmail.com condition early. The clinical symptoms of anaemia can range from mild fatigue to severe cardiovascular complications. However, the relationship between the severity of anaemia and its clinical manifestations remains underexplored, particularly in the context of adult females. Understanding this relationship is essential for improving both diagnostic practices and treatment strategies for anaemia.

Despite the well-known consequences of anaemia, such as fatigue, weakness, and cognitive impairment, there is a lack of comprehensive, observational research that systematically evaluates the clinical presentation of anaemia in adult females, taking into account various underlying factors, such as menstrual history, nutritional intake, and lifestyle. In particular, the variations in how symptoms manifest depending on the severity of anaemia are often not fully understood, which can contribute to delayed or inadequate treatment.

# 1.1. The importance of studying anaemia in adult females

Anaemia in adult females is not only a medical issue but also a socio-economic concern. Related changes, and the higher physiological demands of iron and folate during these periods.<sup>3</sup> Additionally, adult women may also experience anaemia due to chronic diseases like gastrointestinal disorders, chronic kidney disease, or autoimmune diseases.<sup>4</sup>

As such, it is essential to identify and address the root causes of anaemia in this demographic. However, the symptoms of anaemia are often nonspecific and overlap with other conditions, making early diagnosis challenging. Common symptoms include fatigue, pallor, dizziness, and shortness of breath, but the severity and presence of these symptoms can vary significantly from person to person. This can be influenced by the type of anaemia (e.g., iron deficiency anaemia, anaemia of chronic disease, etc.), its etiology, the degree of haemoglobin reduction, and the individual's overall health status.

The manifestations of anaemia in adult women can have a profound impact on quality of life. Even mild anaemia can lead to diminished energy levels, reduced productivity, and impaired cognitive function. In more severe cases, anaemia may result in significant cardiovascular strain, and patients may experience dyspnea, tachycardia, or syncope. Moreover, long-standing untreated anaemia can lead to complications such as heart failure or irreversible cognitive dysfunction. It is, therefore, crucial to understand the clinical manifestations and their relationship to anaemia's severity, as well as to identify any other factors that may influence these manifestations.

Currently, much of the research on anaemia is focused on its prevalence,<sup>6</sup> diagnosis, and treatment in specific populations it includes low and middle income countries.<sup>7</sup> However, few studies specifically address the clinical symptoms and signs in adult females. This gap in knowledge

hinders clinicians from tailoring care for women suffering from anaemia, as there is limited evidence on how women experience anaemia and how these symptoms evolve over time, especially in relation to the severity of the condition.

# 2. Materials and Methods

# 2.1. Study design

This research used a non-interventional, observational design. This indicates that no medical care or diagnostic procedures will be used in this study, this study conducted at Healthcare centres, hospitals, clinics, or primary care settings where adult female patients are seen.

#### 2.2. Duration

This study was Cross-sectional studies collect data at a particular point in time, while longitudinal studies track individuals over a predetermined amount of time. Depending on the goals of the study and the resources at hand, the particular design (cross-sectional or longitudinal) will be chosen.

#### 2.3. Inclusion criteria

In this study adult females aged 18 years and older, Diagnosis of anaemia, established based on haemoglobin levels according to the World Health Organization (WHO) criteria or applicable local guidelines. Specifically, the Haemoglobin levels used to define anaemia will be documented and on provision of informed consent to participate in the study was included.

# 2.4. Exclusion criteria

In this study pregnant or breastfeeding women (due to the distinct physiological changes they undergo), Female with severe co-morbidities (e.g., Cancer, severe Cardiovascular diseases, etc.) that may alters the study results, Female receiving active treatment for anaemia at the time of the study and who was not willing to provide consent was excluded from the study.

#### 2.5. Data collection

Data was collected on the basis of demographic information such as age, ethnicity, socioeconomic status, educational level, etc.

# 2.6. Clinical manifestations

Symptoms shows Fatigue, weakness, dizziness, shortness of breath, palpitations, headache, cold extremities, etc. Signs was Pallor, tachycardia, low blood pressure, reduced exercise tolerance, etc.

#### 2.7. Laboratory data

Haemoglobin levels, haematocrit, red blood cell count, mean corpuscular volume (MCV), and other relevant blood markers. Iron studies (serum iron, ferritin, transferrin saturation) if necessary.

#### 2.8. Medical history

Menstrual history (heavy menstrual bleeding, frequency of periods, age of menarche). History of chronic diseases, nutritional habits, family history of anaemia. Previous blood tests or diagnoses related to anaemia.

Lifestyle Factors: Diet (iron intake, vegetarianism, etc.), exercise habits, use of supplements, smoking, alcohol consumption.

#### 2.9. Methodology

Recruitment: Participants will be identified from clinics and healthcare facilities where adult females present with symptoms or are diagnosed with anaemia.

Data Collection: Participants will complete questionnaires regarding their medical history, lifestyle, and symptoms. Clinical examinations will be performed to assess signs of anaemia in young children's in developing countries.

Laboratory Tests: Blood samples will be taken to confirm the diagnosis of anaemia and measure its severity.

Follow-up (optional): In case of longitudinal studies, patients may be followed for a certain period to assess any changes in their anaemia status and symptoms.

#### 2.10. Data analysis

Descriptive Statistics: Frequencies, means, and standard deviations of clinical manifestations, laboratory parameters, and demographics.

Statistical Tests: Chi-square tests, t-tests, or regression analysis to identify any correlations between severity of anaemia and the clinical manifestations, lifestyle factors, and other variables.

Stratification: Analysis based on different levels of anaemia severity (mild, moderate, severe) and comparison of symptom prevalence across these groups.

#### 2.11. Outcome measures

Primary Outcome: Prevalence and frequency of specific clinical manifestations (e.g., fatigue, pallor) in adult females with anaemia.

Secondary Outcome: Identification of factors (age, menstrual history, lifestyle, pregnancy) that influence the clinical manifestation of iron deficiency anaemia.

# 3. Results

**Table 1** shows the statistics of demographics in which parameter such as gender, age, height, weight and BMI mean will be shown in which all participants were female (n=40), accounting for 100% of the sample. No males were included in the study. The average age of participants was 39.43 years, with a standard deviation (SD) of 9.77 years. The average height of participants was 1.65 meters, with an SD of 0.06

meters. The average weight was 64.63 kilograms, with an SD of 4.77 kilograms. The average Body Mass Index (BMI) was 28.23 kg/m², with an SD of 3.39 kg/m², indicating that the group is on average slightly overweight.

**Table 1**: Summary statistics of demographics

Parameter	Mean ± SD		
Gender	Male (n=0) 0% Female (n=40) 100%		
Age	$39.43 \pm 9.77$		
Height (Mts)	$1.65 \pm 0.06$		
Weight (Kgs)	$64.63 \pm 4.77$		
BMI (Kg/m <sup>2)</sup>	$28.23 \pm 3.39$		

**Table 2**: Summary statistics of vital signs

Parameter	Mean ± SD
Pulse Rate	$90.48 \pm 11.54$
Respiratory Rate	19.43 ± 1.55
SBP	$120.28 \pm 7.39$
DBP	$81.53 \pm 7.16$
Temperature	$98.03 \pm 0.53$

In **Table 2** we shows the statistics of vital signs, in which the average pulse rate was 90.48 beats per minute, with a standard deviation (SD) of 11.54. The average respiratory rate was 19.43 breaths per minute, with an SD of 1.55. The average systolic blood pressure was 120.28 mmHg, with an SD of 7.39. The average diastolic blood pressure was 81.53 mmHg, with an SD of 7.16 and the average body temperature was 98.03°F, with an SD of 0.53.

Table 3: Summary statistics of clinical investigations

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Mean ± SD				
$11.53 \pm 15.36$				
$4.62 \pm 0.35$				
$6181.00 \pm 970.61$				
$2.88 \pm 0.44$				
$57.55 \pm 4.24$				
$37.13 \pm 4.37$				
$2.98 \pm 0.80$				
$2.35 \pm 0.86$				
$0.00 \pm 0.00$				
$56.93 \pm 4.73$				
3.29				

**Table 3** shows the statistics of clinical investigation done during the study, in which the average haemoglobin level was 11.53 g/dL, with a high standard deviation (SD) of 15.36, indicating variability in the data. The average red blood cell (RBC) count was 4.62 million cells per microliter, with an SD of 0.35. The average white blood cell (WBC) count was 6181.00 cells per microliter, with an SD of 970.61. The average platelet count was 2.88 lakh cells per microliter, with an SD of 0.44. The average neutrophil percentage was 57.55%, with an SD of 4.24. The average lymphocyte

percentage was 37.13%, with an SD of 4.37. The average eosinophil percentage was 2.98%, with an SD of 0.80. The average monocyte percentage was 2.35%, with an SD of 0.86. The average basophil percentage was 0.00%, with no variability (SD = 0.00), suggesting none were detected in the sample. The average serum iron level was 56.93  $\mu g/dL$ , with an SD of 4.73. The average ferritin level was 24.25 ng/mL, with an SD of 3.29.

**Table 4** shows that Statistics of Lifestyle Factors which included 82.5% (33 participants) reported fatigue, while 17.5% (7 participants) did not reported fatigue, 85% (34 participants) reported weakness, while 15% (6 participants) did not, 82.5% (33 participants) reported dizziness, while 17.5% (7 participants) did not, 75% (30 participants) reported shortness of breath, while 25% (10 participants) did not, 92.5% (37 participants) reported palpitations, while 7.5% (3 participants) did not, 82.5% (33 participants) reported headaches, while 17.5% (7 participants) did not, 85% (34 participants) reported cold extremities, while 15% (6 participants) did not, 50% (20 participants) reported iron intake, while the other 50% (20 participants) did not, 0% (0 participants) smoked, and 100% (40 participants) did not, 0% (0 participants) consumed alcohol, and 100% (40 participants) did not, 30% (12 participants) followed a vegetarian diet, while 70% (28 participants) did not and 20% (8 participants) exercised daily, while 80% (32 participants) did not.

**Table 5** shows the Haemoglobin V/S Serum Iron has t-test value is 17.87 with a p-value < 0.00001, which indicates a significant correlation between haemoglobin levels and serum iron levels (p < 0.05) while Haemoglobin vs Ferritin has t-test value is 5.12 with a p-value < 0.00001, which also indicates a significant correlation between haemoglobin levels and ferritin levels (p < 0.05).

# 4. Discussion

The data presented highlights several key aspects of the participants' demographics, clinical investigations, lifestyle factors, and their relationship with anaemia severity. The study predominantly involved females (100%) with a mean age of 39.43 years.<sup>8</sup> The participants had an average BMI of 28.23 kg/m², indicating that they were slightly overweight, which could have implications for their overall health and the presence of conditions like anaemia.<sup>9</sup> The average weight and height further suggest that the group had a generally healthy

physical profile, but with impact of health factors like overweight status. 10

The participants exhibited vital signs that are generally within the normal range, though the average pulse rate was somewhat elevated (90.48 bpm), indicating mild tachycardia, which may be linked to anaemia, as the body compensates for reduced oxygen levels. The systolic and diastolic blood pressure readings were also within normal limits, as was the body temperature.

The average haemoglobin level of 11.53 g/dL, though within the low normal range, showed a significant variability (SD = 15.36), which could indicate a diverse range of anaemia severity across participants. The RBC count, WBC count, and platelet count were all within normal limits, but the serum iron and ferritin levels (56.93  $\mu$ g/dL and 24.25 ng/mL, respectively) were on the lower end, confirming an iron-deficiency, status among the participants. This suggests that anaemia in this group is likely related to insufficient iron stores.  $^{11}$ 

A large proportion of participant's dietary causes reported symptoms such as fatigue (82.5%), weakness (85%), dizziness (82.5%), and cold extremities (85%), which are common manifestations of anaemia.<sup>12</sup> Additionally, 92.5% reported palpitations, 13 indicating cardiovascular stress, which is consistent with anaemia's effects on the heart and circulation. It is noteworthy that 50% of the participants reported iron intake, indicating that nutrition through life cycle, might be a contributing factor to their iron-deficiency anaemia. 14-16 However, the WHO says, absence of smoking or alcohol consumption in the group suggests that lifestyle factors related to these behaviours do not play a role in the anaemia observed in this cohort. Moreover, only 30% of participants were vegetarian, which could be a risk factor for iron deficiency, considering the limited availability of haeme iron in vegetarian diets. 17,18

The t-test results reveal significant correlations between haemoglobin levels and both serum iron (p < 0.00001) and ferritin (p < 0.00001). This suggests that low haemoglobin levels are strongly associated with low serum iron and ferritin levels, which are key indicators of iron-deficiency anaemia. These findings align with the clinical manifestations of anaemia observed in the participants, such as fatigue, dizziness, and palpitations.

**Table 4**: Summary statistics of lifestyle factors

Parameter	Yes Mean ± SD	No Mean ± SD
Fatigue	33 (82.5%)	7 (17.5%)
Weakness	34 (85%)	6 (15%)
Dizziness	33 (82.5%)	7 (17.5%)
SOB	30 (75%)	10 (25%)
Palpitations	37 (92.5%)	3 (7.5%)
Headache	33 (82.5%)	7 (17.5%)

Cold extremities	34 (85%)	6 (15%)
Iron intake	20 (50%)	20 (50%)
smoking	0 (0%)	40 (100%)
Alcohol consumption	0 (0%)	40 (100%)
Vegetarian	12 (30%)	28 (70%)
Exercise Habits	8(20%)	80%)

**Table 5:** t-tests analysis to identify any correlations between severity of anemia and the clinical manifestations

Mean-1	Mean-2	<i>t</i> -value	<i>p</i> -value	Result
Haemoglobin (11.53)	Serum Iron (56.93)	17.86702	< 0.00001	Significant at $p < 0.05$
Haemoglobin (11.53)	Ferritin (24.25)	5.12256	< 0.00001	Significant at $p < 0.05$

#### 5. Conclusion

study investigated the relationship demographics, clinical manifestations, lifestyle factors, and the severity of anaemia in a group of 40 female participants in which we find High prevalence of iron-deficiency anaemia, with low haemoglobin, serum iron, and ferritin levels, Significant correlation between haemoglobin, serum iron, and ferritin, highlighting iron's role in anaemia, Lifestyle factors, such as inadequate iron intake and vegetarian diet, contributed to anaemia, High prevalence of symptoms like fatigue, weakness, and palpitations and Iron supplementation and dietary adjustments are necessary to address deficiencies. The study emphasizes the need for public health interventions to improve iron intake, particularly in at-risk groups, and highlights the importance of monitoring iron levels in individuals with low haemoglobin levels.

#### 6. Informed Consent

All participants will sign an informed consent form, the form will clearly explain the nature of the study and Participants will be given the opportunity to ask questions.

# 7. Confidentiality

All personal and medical information will be kept confidential, Confidentiality will be maintained in compliance with local regulations and Examples of relevant regulations include HIPAA (HIPAA (Health Insurance Portability and Accountability) and GDPR (General Data Protection Regulation).

# 8. Ethical Approval

The study will undergo ethical review and Review will be conducted by an institutional review board (IRB) or ethics committee and Ref: 2024/12/01

# 9. Conflict of Interest

None.

# 10. Source of Funding

None.

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